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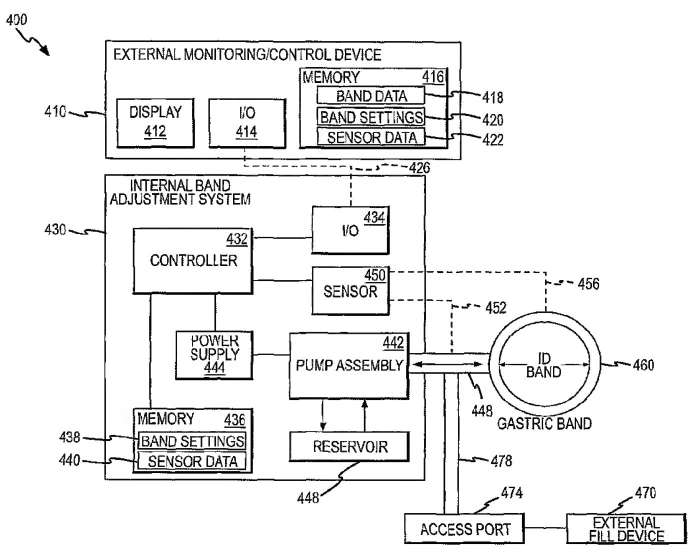

(57) Abstract: A self-regulating gastric band apparatus for adjusting stoma size in a patient. The apparatus includes an adjustable gastric band that has an expandable inner ring with a lumen or cavity for receiving a fluid. A band adjustment assembly is provided for implanting with the gastric band that includes a sensor for sensing a property of the gastric band, such as of the expandable inner ring. The band adjustment assembly further includes a pump assembly connected to the lumen of the expandable inner ring and to a controller that can operate the pump assembly to adjust the volume of the fluid in the lumen based on the sensed gastric band property. The band adjustment assembly includes memory storing an operating range for the particular band property, and the pump assembly is operated to maintain the sensed band parameter within the operating range.

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SELF-REGULATING GASTRIC BAND

BACKGROUND OF THE INVENTION

1. Field of the Invention.

The present invention relates, in general, to devices and methods for controlling obesity, and, more particularly, a gastric band or gastric band assembly/system, and corresponding methods, configured for self-monitoring and adjustment of the size, i.e., internal diameter, of the gastric band so as to provide ongoing adjustment of stoma size in a patient.

2. Relevant Background.

Severe obesity is an increasingly prevalent chronic condition that is difficult for physicians to treat in their patients through diet and exercise alone. Gastrointestinal surgery is used by physicians to treat people who are severely obese and cannot lose weight by traditional means or who suffer from serious obesity-related health problems. Generally, gastrointestinal surgery promotes weight loss by restricting food intake, and more specifically, restrictive operations limit food intake by creating a narrow passage or "stoma" from the upper part of the stomach into the larger lower part, which reduces the amount of food the stomach can hold and slows the passage of food through the stomach. Initially, the stoma was of a fixed size, but physicians have more recently determined that the procedure is more effective if the stoma can be adjusted to alter its size.

One of the more commonly used of these purely restrictive operations for obesity is adjustable gastric banding (AGB). In an exemplary AGB procedure, a hollow band (i.e., a gastric band) made of silicone elastomer is placed around the stomach near its upper end, creating a small pouch and a narrow passage (i.e., a stoma) into the rest of the stomach. The band is then inflated with a saline solution by using a non-coring needle and syringe to access a small port that is placed under the skin. To control the size of the stoma, the gastric band can be tightened or loosened over time by the physician or another technician extracorporeally by increasing or decreasing the amount of saline solution in the band via the access port to change the size of the passage or stoma.

Providing fine adjustments of the gastric band after initial stoma sizing has proven a significant improvement in the adjustable gastric banding procedure. However, there is an ongoing difficulty in determining when to further adjust the gastric band and how much to increase or decrease the bands size or diameter to achieve a desired stoma size. Numerous gastric bands have been developed to allow a physician or other technician to adjust an implanted gastric band. In general, these band systems include a sensor for measuring or determining parameters associated with the patient and in response, the physician or technician acts to adjust the volume of fluid in the band based on the patient parameters. For example, one adjustable gastric band system determines when the pressure in a patient's stomach exceeds a pre-set limit and provides an alarm to an external control device. A doctor or other operator then responds by loosening the gastric band by removing an amount of fluid from the band via the external access port and fill line. In another gastric band system, components for adjusting the size of the gastric band are implanted within the patient, and when a physical parameter related to the patient, such as stomach pressure or the physical position of the patient, are determined, an external control unit outside the patient's body is operated to power the implanted components to adjust the size of the band, e.g., by adding or removing a preset volume of fluid from the band.

While providing improved control over adjustable gastric bands, the existing gastric bands do not meet the needs of patients. In part, the deficiencies in the existing adjustable gastric bands are due to the need for the patient to be treated by a doctor or other technician to adjust the size of the gastric band and the formed stoma via an external control unit. Other deficiencies are related to the unreliability or inaccuracy of sensing parameters related to the patient and correlating this to a desired stoma size. Further, some of the existing gastric bands require insertion of sensors into the patient, such as into or onto the stomach to determine stomach pressure. Due to these and other limitations of existing technologies, there remains a need for an improved gastric banding system, and associated adjustment methods, for providing improved adjustments to the size of a stoma in a patient being treated for obesity.

SUMMARY OF THE INVENTION

The present invention addresses the above and other problems by providing a self-regulating gastric band system for implanting in an obese patient to automatically adjust the

size of a stoma on a periodic or ongoing basis. The system is "self-regulating" in some embodiments as it includes a sensor for sensing a property or parameter of an implanted expandable gastric band and a band adjustment assembly or system that adjusts the size of the expandable gastric band in response to the sensed band property. For example, a physician or clinician may set an operating range for the property in memory of the system prior to implanting or after via an external control device. The sensor operates to periodically, on an ongoing basis, or upon being activated to sense the band property (such as fluid pressure within an expandable inner ring or member of the band). The sensor or a controller operates to determine if the band is within the desired range based on the sensed band property, and if not, the controller acts to adjust the size of the band to bring the band or its sensed property back into the operating range, such as by operating a pump assembly to move fluid between a fluid reservoir and the expandable inner ring. The self-regulating gastric band system typically also includes a housing for enclosing the system components implanted with the gastric band and a local power source that is implanted to provide power to various system components such as pumps, the sensor, and the controller. In this manner, embodiments of the gastric band system may be considered "set-it and forget-it" gastric banding treatments for obesity.

More particularly, a self-regulating gastric band apparatus is provided for adjusting stoma size in a patient. The apparatus includes a gastric band for implanting in a patient. The gastric band has an expandable inner ring with a lumen or cavity for receiving a fluid (such as saline). A band adjustment assembly is provided for implanting with the gastric band, and this assembly includes a sensor for sensing a property or parameter of the gastric band, and more typically, of the expandable inner ring (e.g., the pressure of the fluid in the inner ring or other property indicative of the inner ring's size and therefore, of the size of the gastric band). The band adjustment assembly further includes a pump assembly connected with the lumen of the expandable inner ring and a controller that can operate the pump assembly to adjust the volume of the fluid in the lumen based on the sensed gastric band property. The band adjustment assembly may include memory storing an operating range for the particular band property (such as an upper and lower limit defining an acceptable operating range, e.g., two fluid pressure values defining an upper and lower bound of a pressure range), and in this case, the controller (or a programmable sensor) compares the

sensed band property to determine if it is within the operating range. If not, the controller operates the pump assembly to either increase the volume of fluid in the inner ring or to decrease the volume of fluid depending on whether the sensed parameter is out of range low or high.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 illustrates a self-regulating (i.e., self-monitoring and self-adjusting) gastric band system according to the present invention as it may appear when installed in a patient;

Fig. 2 illustrates a gastric band with an interconnected internal band adjustment system in fluid communication with lumens of the band such as may be used in a self-regulating gastric band system such as in the system of Fig. 1;

Fig. 3 is a cross sectional view of the gastric band of Fig. 2 taken at line 3-3 illustrating the inner, expandable lumen used for fine tuning the inner diameter or size of the gastric band and an outer lumen providing a local or internal reservoir for fluid for use in expanding (and deflating or shrinking) the inner, expandable lumen;

Fig. 4 is a functional block diagram of a self-regulating gastric band system according to one embodiment of the invention;

Fig. 5 is a schematic and/or functional block diagram of another embodiment of a self-regulating gastric band system of the invention illustrating more particularly one embodiment of a pump assembly useful for implementing the self-adjusting features of the invention;

Fig. 6 is a cutaway perspective view of one physical implementation of the pump assembly of the invention, and particularly, of the pump assembly of the system of Fig. 5;

Fig. 7 is a schematic diagram similar to Fig. 5 showing another embodiment of a self-regulating gastric band system of the invention that uses a different pump assembly than the system of Fig. 5;

Fig. 8 is a schematic diagram similar to Figs. 5 and 7 showing yet another embodiment of a self-regulating gastric band system of the invention using a pump assembly that differs from those shown in the systems of Figs. 5 and 7;

Fig. 9 is a schematic diagram similar to Figs. 5, 7, and 8 that illustrates another embodiment of a self-regulating gastric band system of the invention using yet another pump assembly useful for practicing the adjusting features of the invention;

Fig. 10 is a schematic diagram similar to Figs. 5, 7, 8, and 9 that shows still another embodiment of a self-regulating gastric band system of the invention using a pump assembly and sensor location relative to the systems of Figs. 5, 7, 8, and 9;

Fig. 11 is a functional block diagram of self-regulating or adjusting gastric band system of the invention utilizing a handheld controller communicating with remote controllers or services (such as web page-based controllers or services) via a telephone link;

Fig. 12 is another functional block diagram showing the handheld controller and cradle of the system of Fig. 11 in additional detail;

Figs. 13 and 14 are perspective views of an exemplary implementation of a handheld controller and cradle according to the present invention, such as to implement the systems of Figs. 10 and 11; and

Fig. 15 is a flow chart of a normal mode of operating gastric band system, such as those described in Figs. 10 and 11, to regulate the size of an implantable gastric band.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

In brief, the invention is directed to a self-regulating gastric band or band system that enables an operator (e.g., a physician or technician) to set operational parameters for a gastric band prior or after implantation in a patient. The self-regulating gastric band then is operable to directly monitor properties of or associated with the gastric band, to determine if these monitored or sensed properties are within the set operational parameters or bounds, and then, if not within the bounds, to automatically adjust the size of the gastric band (i.e., its inner diameter that establishes the size of a stoma in the patient's stomach) such that the monitored or sensed property or properties are within the present operation range or bounds.

Self-regulating gastric band systems of the invention generally can be used with numerous gastric band designs with many embodiments being particularly useful for those that include an inflatable portion or inner lumen that is expanded or contracted by increasing or decreasing the volume of fluid contained therein. Generally, the gastric band systems of the invention include one or more sensors for directly sensing a band parameter, such as pressure of the fluid in the inflatable portion, and a controller that processes this sensed band parameter or property to determine whether to add or withdraw fluid from the band to finely tune its size (and the corresponding stoma size). A local fluid reservoir may be provided that is connected to a pump assembly, which is controlled by the controller to pump fluid into or out of the band. In one embodiment, the local fluid reservoir is provided within the gastric band itself, e.g., in an outer lumen or reservoir ring or member. An internal fill line or tube is connected between the pump assembly and the inflatable portion or member of the gastric band to allow the volume to be controlled locally (e.g., instead of or in addition to a standard access port). Power for the pump assembly, controller, and sensor is typically also provided local to the gastric band, i.e., intracorporeally or adjacent the stoma and gastric band in the patient, rather than from an external power source such as an induction power source. Memory is also associated with the controller to store band data and band operating ranges or bounds that are used to determine when to adjust the size of the gastric band, and these operating ranges or bounds (i.e., range limits) may be set before implantation or later set or modified via communications with an external controller/monitor. These and other features of the invention are described in detail in the following description with reference to Figures 1-10.

Figure 1 illustrates a self-regulating gastric band system or apparatus 100 as it may appear when installed in a patient being treated for morbid obesity. As shown, the system 100 is being used to form a stoma or smaller opening in the upper portion of the stomach near the esophagus to restrict food intake and flow. It is often useful or even necessary to vary the size of the stoma to properly treat a patient. Hence, the self-regulating gastric band system 100 is adapted for self-regulation of its size based on sensed band parameters and operating parameters (such as a range of operating parameters with set upper and lower limits). The gastric band system 100 includes a gastric band 110 that is inflatable by external or extracorporeal actions via a fill tube or line 112 that is connected to an access

port 114 through which fluid can be pumped into the inflatable portion or member of the gastric band 110. Such a filling if typically performed as part of an initial sizing of the stoma as part of the implanting process performed by the physician or other technician.

The band 110 and other components of the system 100 are implanted in the same or similar surgical procedure as used with existing expandable or inflatable gastric bands. For example, a surgeon would typically dissect the tissues around the stomach to create a tunnel for the band 110. The band 110 is then introduced into the patient's abdomen, e.g., through a 18 mm or other sized trocar or the like or directly through the trocar hole in the skin. The band 110 is then tunneled in place and positioned around the stomach. The other components of the system 100 including the internal band adjustment system or unit 130 are placed near the stomach (such as just below the skin on top of the sternum or on the rectus muscle sheath proximate the access port) with fluid connection provided via fill/drain line 120 to the gastric band 110 and particularly to the inflatable or expandable member or portion of the band 110 (additional connections are provided in embodiments in which the band 110 also includes a local fluid reservoir for use in sizing the band 110). In other embodiments, the connection 120 is provided to the fill line 112 such that another connection to the band 110 is not required.

The self-regulating gastric band system 100 includes an internal band adjustment assembly or unit 130 that functions to sense a band parameter, such as fluid pressure in the inflatable or expandable portion or lumen or in the fill line 112 or a property such as surface tension/strain on the band or the like, to determine if this sensed or monitored band property or parameter is within a predefined acceptable band operating range, and if not, to adjust the size of the gastric band 110. Typically, the size adjustment is achieved via the fill/drain line 120 by adding or removing liquid, such as saline, to or from the band 110, which is explained in detail with reference to Figures 4-10. The system 100 further includes an external monitoring or control device 150 that includes a display element 154 that is used to display data received via wireless communications 152 with the internal band adjustment system or unit 130, to display data such as new operational parameters to be sent to the internal system 100, or to display historic or other data associated with the gastric band 110. The external monitoring device 150 also includes a keypad or other input area 156 for allowing an operator to enter data or input (such as to request data from the internal system

130, to input a new setting for the gastric band 110 by adjusting its operating range, or the like).

The gastric band 110 may take many forms to practice the invention. For example, but not as a limitation, the gastric band 110 may be configured similar to the gastric bands described in U.S. Patent Nos. 5,226,429 and 5,601,604, which are incorporated herein in their entirety by reference. Alternatively, the gastric band 110 may include one of the gastric bands available from Inamed Corporation (e.g., one of the bands in the LAP-BAND™ family of expandable gastric bands such as the 9.75, 10.0, 11.0 cm, the VG, or AP LAP-BANDs). Other gastric bands from various band manufacturers/distributors that could be used for this application include, but are not limited to: the Obtech (Ethicon) band, the AMI band, the Heliogast band, the Minimizer (Pier) band, and Cousin Bioband.

Figures 2 and 3 illustrate an embodiment of a self-regulating gastric band assembly 200 that includes one exemplary gastric band 210 that may used to implement the invention (such as for use as band 110 in system 100). The gastric band assembly 200 includes the gastric band 210 and an internal adjustment system 230, as described with regard to Figure 1 and in more detail with Figures 4-10, that generally in includes a sensor(s) for directly sensing properties of band 210, a controller with memory, an internal power supply, and a pump assembly (not shown in Figures 2 and 3 but described with reference to Figures 4-10).

The gastric band 210 includes a fill tube or line 212 that is used to provide a fluid connection between an access port (not shown) and an expandable or inflatable portion or lumen 226 in the band 210. A belt 214 with a recessed surface 215 and raised portion 218 are provided along with a buckle member 216 to allow initial forming of a circular loop or band of a particular initial size or inner diameter when the band 210 is implanted about a patient's stomach (e.g., to initially set the size to the band at 9 to 11 cm or another useful inner diameter) to provide an initial size of a stoma. To allow additional fine adjustment of the stoma, the gastric band includes an inflatable portion or member that abuts the outer surfaces of the stomach.

As shown, the gastric band 210 includes a shell or molded shell 220, an inner ring 222, and an inflatable portion, member, or balloon 224 made of an elastic or other material that can be increased in size and later reduced in size. The inflatable member 224 includes

an internal lumen 226 for received volumes of fluid, e.g., saline or the like. According to one feature of the invention, the gastric band 210 may be configured to provide a local fluid reservoir for storing fluid for expanding or deflating the inflatable portion 224. In this regard, the inner ring 222, which is typically made of a more rigid material than the inflatable member 224 and is attached at 321 (such was with adhesive) to the shell 220, includes a lumen or reservoir 323 for storing fluid that later can be pumped into the lumen 226 of inflatable portion 224 by the internal adjustment system 230. The lumen or reservoir 323 is useful as a store of fluid because reservoir connection tube or line 238 is provided to the internal band adjustment system 230 (such as to a pump (not shown) in the system 230).

Fluid removed from the reservoir 323 formed by inner ring 222 is pumped via line 340 to the internal band adjustment system 230 to the lumen 226 of the inflatable member 224 to increase the size of the gastric band (i.e., increase the outer diameter of a cross section of the band 210 as shown in Figure 3) or to reduce the size of the ID formed by the band about the stomach to reduce the size of the stoma formed in a patient. At other times, the internal adjustment system 230 is operated (based on sensed band parameters) to pump fluid from the lumen 226 as shown by arrow 350 via fill/drain line 234 which connects the lumen 226 of the inflatable portion 224 to the internal band adjustment system 230 (or to a pump in the system 230). Such removal of fluid from lumen 226 decreases the size of the band 210 and inflatable member 224 while increasing the ID formed by the band 210 about the stomach and increasing the size of the patient's stoma. The fluid removed from the inflatable portion 224 is pumped into the reservoir 323 as shown by arrow 340 for storage and later use in sizing or adjusting the gastric band 210.

Figure 4 illustrates in functional block form an exemplary self-regulating gastric band assembly or system 400. The system 400 includes an external monitoring and/or control device 410 that communicates wirelessly 426 with an internal band adjustment system 430. In use, the internal band adjustment system 430 is implanted along with an expandable or adjustable gastric band 460 in an abdominal cavity of a patient to form a stoma in the patient's stomach to treat obesity, i.e., the gastric band is inflated or deflated by the addition or withdrawal of fluid to change the size of the gastric band and the inner diameter of the band, ID_{BAND}, formed by the band in its circular configuration. The external monitoring and control device 410 may take the form of a handheld, laptop, or desktop

computer and/or communication device that includes a display element 412 for displaying information, an input/output components 414 for allowing a user to input data or information such as a keypad, touchscreen, and/or voice data entry feature and for wireless communications as shown at 426 with an I/O component of the internal band adjustment system 430. The device 410 further includes memory 416 for storing band data 418, such as may be read from system 430 and provided by controller 432 and I/O 434 of internal system 430 and for storing band settings 420, such as operation ranges or bounds (i.e., an upper and lower limit such as for a pressure range) for the gastric band 460 that may be entered with the control device 410 or present in the internal system 430 and later read by the external device 410 for storage in memory 416 and/or for modification or alteration by operation of the external control device 410. The memory 416 may also be used by the external control device 410 for storing sensor data 422 (and, in some cases, patient data) obtained by the sensor 450 of the internal band adjustment system 430.

The internal band adjustment system 430 is shown to include a controller 432, which may include a CPU and code useful for controlling operation of the system 430. The system further includes an I/O element 434 for communicating with the external monitoring and control device 410. Memory 436 is provided in the system 430 for storing band settings 438, i.e., an acceptable operating range for a particular property or parameter of the gastric band 460 that is sensed by the sensor 450 such as an upper or lower pressure limit (e.g., 4 and 5 PSI) when the sensor 450 is a pressure sensor for the fluid in the inflatable portion of the gastric band 460. The band settings 438 may be set for the particular patient or as default settings prior to implanting the system 430 in a patient and/or the band settings 438 may be set or modified after implanting via the external monitoring/control device 410 so as to alter the size of the gastric band 460 and the resulting inner diameter, ID_{BAND}. The memory 436 may also be used by the controller 432 for storing other sensor and band data 440 such as data collected from the sensor 450 to provide a historical perspective of operation of the gastric band 460 and band information such as band serial number, manufacturer, and the like.

To monitor operation of the gastric band 460, the system 430 includes the sensor 450 which preferably monitors directly properties or physical parameters of the gastric band 460. As shown, the sensor 450 may be provided in or linked to as shown at 452 a pressure

transducer or other device in a fluid link or connection 448 between the gastric band 460 and the pump assembly 442 of the system 430. Alternatively, a pressure transducer or other pressure sensing device may be provided as sensor 450 or in communication with the sensor 450 to measure pressure in the gastric band 460 such as by positioning in the inflatable portion of the band 460, at an inlet port to the band 460, in the fill line 478 which is in communication with access port 474 and external fill device 470 (which, in turn, is provided for initial filling of inflatable or expandable portion of the band 460 or for optional later adjusting of the band 460). The sensor 450 may also be positioned so as to otherwise directly sense properties of the band 460 such as shown with line 456, e.g., with a strain sensor indicating surface tension of the band 460 such as on a surface of the inflatable or expandable portion or with other sensing devices useful with measuring the present size of the gastric band 460.

The sensor 450 may include the memory 436 or memory for storing the band settings 438 such that when it senses a parameter of the band 460 that is outside a preset range (such as above a maximum setting or below a minimum setting) the sensor 450 may "wake up" the controller 432 to operate the pump assembly 442. In other words, the sensor 450 may be configured to be intelligent enough to determine when the gastric band 460 is outside a preset operational range and respond by alerting or alarming to cause the controller 432 to operate to control the pump 442 including transmitting the sensed band parameter to allow the controller 432 to act appropriately to adjust the band 460. Alternatively, the sensor 450 may be periodically (or, in some cases, more frequently as to approach nearly continuous) operate the sensor 450 to take an additional reading of the band property or parameter (as shown as 452 and 456) and to provide the sensed value to the controller 432 which, in turn, acts to compare the sensed band value with the band settings 438 to determine if adjustments of the band 460 are required or desired.

In either case, a power supply 444 such as a battery or the like is used to power the controller 432 and other power consuming components of the system 430 (such as the pump assembly 442 and the sensor 450). The system 430 further includes pump assembly 442 and an internal reservoir 446. The pump assembly 442 may take a variety of forms (such as those shown in Figures 5-10) to hydraulically adjust the size of the band 460 in response to sensor 450 information and the invention is not limited to one particular pump or fluid

transfer device. The internal or local reservoir 446 is in fluid communication with the pump assembly 442 and provides fluid (such as saline) for pumping via fill/drain line 448 into the band 460 to increase its size and reduce the ID_{BAND} and also provides a location for storing fluid that is pumped or allowed based on pressure differentials from the band 460 via the line 448 and pump assembly 442. The reservoir 446 may be provided as a separate component in a housing (not shown) that is used to enclose or encapsulate the internal band adjustment system 430 or the reservoir 446 may be provided as a separate device, such as in the form of a balloon-like structure, that is provided proximate the system 430 housing and the band 460. Further, in some embodiments, the reservoir 446 may be provided as part of the gastric band 460 itself such as in an outer lumen or member of the band shell (as is shown in Figures 2-3 and Figures 5-10).

With an understanding of the general features of self-regulating gastric band systems, it may be useful now to more fully discuss operation of such systems to effectively adjust the size of an implanted gastric band (such as bands 110, 210, and 460). The pump assembly is typically modular and can be used with any of number of gastric bands, e.g., those currently available from Inamed Corporation such as the 9.75 cm, 10.0 cm, VGs, or APs LAP-BANDs. The pump in the pump assembly replaces the function of the manually adjustable access port. The materials used to construct the band will generally remain the same as normally employed, and the dimensions of the band, except the tubing in the case of a local reservoir being provided in the shell or tubing, will remain the same. However, alternate materials may be used to implement the invention such as materials selected specifically to improve performance, to increase acid resistance, or to achieve some other desired result. Similarly, there may be a minor change to the band tubing to increase the outer diameter from .130 to .180 or greater to increase saline capacity in the outer or shell lumen or tubing to act as a reservoir for additional saline or fluid that may be used for future adjustments. The tubing of the gastric band may have 2 lumens to separate the saline for the reservoir and saline that is part of the band (as is shown in Figures 2 and 3). In addition, a long extended balloon may be placed along the tubing to act as a reservoir. The pump assembly will generally include one or more pumps (or pump-like devices for moving fluid in and out of the band), electronics, communication components, computer or intelligence components, and a power supply such as a battery or batteries. The internal gastric band

adjustment assembly will be sealed inside an outer housing made of a biocompatible material such as acetyl copolymer, PEEK, titanium, or the like. In some embodiments, the power supply is an implantable grade battery that is hermetically sealed in titanium prior to being placed into the pump assembly. The pump assembly may have an over-ride port that will allows for manual adjustments if needed such as with external fill device 470 via access port 474 shown in Figure 4.

In some preferred embodiments, the self-regulating gastric band system functions automatically or as a "set-it-and-forget-it" device. For example, the system may function may continually or periodically (such as hourly, daily, weekly, monthly, or some other selected monitoring period) sense a band parameter or property and then adjust such as via inflating and deflating the gastric band hydraulically with saline or another fluid. In some cases, the same or similar specification for saline fill volume and a fill burst of the band will apply to the self-regulating gastric band system. The adjustments in these self-regulating embodiments are performed by the remote actuation of a micropump or pumps coupled with the sensor and with control electronics. The sensor detects directly a parameter or property of the band such as an internal parameter of the band, e.g., an internal band pressure, or an internal or external parameter such as stress and/or strain of the shell. The sensor may also include a linear motion sensor that detects changes in length in the band or in the inflatable portion of the band, with the sensor or controller acting to convert this detected length delta to stoma or band diameter measurements. The sensor may also be a distance sensor functioning to detect the distance between two points to detect a change in position. The sensor could be queried by an external monitoring or control unit via telemetry to gather data on the parameter being monitored for real time feedback to the clinician.

In some cases, the sensor is programmed to "wake up" at intervals (or monitoring periods) to monitor parameters and to adjust the band to the ideal band parameter(s) established through testing or established to better treat a patient over a longer treatment period. If the parameters are not within the ideal range, the sensor will send a command to re-adjust as necessary to ensure that the band reads within the ideal parameter control limits or alternatively, the sensor will merely pass the gathered information from the band to the controller for use in determining whether the band is in a desired operating range. For example, the sensor may "wake up" and determine that the band is monitoring an internal

band pressure of "X psi" and determine based on a comparison with preset band parameters that the band needs to be adjusted such that its internal fluid pressure is at "Y psi" which may be a pressure at the midpoint within an operating range or any pressure within that range. The sensor, in this arrangement, will communicate to the controller to cause the controller to activate the implanted pump and command the volume of fluid to be pumped into band or out of the band until the sensor reads within ideal parameter limits, e.g., by operating the pump until the sensor detects an internal fluid pressure in the band within the range or matching the midpoint of the present operating range (or other reset point saved in memory associated with the sensor or with the controller).

The micropump(s) draw power from the implanted battery or power supply to allow for the adjustment and, if included, the controller also activates one or more check valves to open (see Figures 5-10). To inflate the band further or to finely increase its size, the pump pulls fluid from the local reservoir into the band. To deflate the band or to finely decrease its size, the pump will pull fluid from the band back into the reservoir. Once the sensor reads within the specified parameter range, the valves will close to prevent fluid migration. The pump and sensor will then be shut off to conserve power until the sensor "wakes up" again. Just as in current bands, fluid will be used to either inflate or deflate the shell to control the stoma size but in this case the change in size is handled internally using local control and a local fluid reservoir. After the parameter monitored by the sensor has been changed, the sensor will send a command or message to the controller to record the date the parameter was changed, the value of the new setting or sensed band parameter or property, and, in some cases, the delta or amount of the change.

To externally monitor a parameter reading such as a new or adjusted parameter reading from the sensor, a clinician or operator of the system can use a handheld or other sized external monitor and control device external to the patient's body to query the sensor for a reading or to query the controller for a most recently stored value (or both). Aside from the external monitor device and access port, the system is self-contained to monitor and adjust itself. The pump assembly may store a variety of data in addition to the band data and acceptable band operating range such as a serial number that can be remotely read by the external monitoring and control device to identify the implanted device including the implanted gastric band and internal gastric band adjustment system.

The external device often will take the form of a handheld control unit that may feature an LCD display and control panel to operate the device. The handheld may feature a series of menus that allow an operator to program (or read/determine) the implant to contain in memory important information such as the band size, patient's name, implanting physician, and the date it is implanted. The handheld may communicate with the sensor via telemetry through radiowaves. The FDA and globally recognized communications band (WMTS 402 – 405 Mhz) may be used in some embodiment, and an authentication process can be used to ensure that the device cannot be accidentally accessed or controlled by another control mechanism other than the handheld. The telemetry control signal can be sent from approximately a foot or possibly a greater distance from the patient and will typically not require the patient to disrobe to query the sensor or to change its parameters. During adjustments, the handheld external monitoring device is preferably able to read and write information to the implant such as current pressure or parametric data, adjusting physician's name, the date with the handheld device often operating to store or retain the adjustment history in its own memory (this history can be stored in the internal adjustment system, too or only). The handheld device may also be password controlled to prevent unauthorized personnel from querying the device. The display of the handheld, which may include visual and audio outputs, typically will display or output the sensed parameter of the band's condition or physical parameter whether this parameter or property is pressure, stress, strain, and/or linear measurement.

As to the sensor change duration, the sensor query typically will only take a few seconds, but the control of the micropump(s) may take longer, such as approximately 30 seconds per 1 psi of pressure change. The resolution of pressure readings and parameter ranges will be fine and preferably will have greater resolution than is currently possible by manual syringe adjustments. Regarding data storage, at least a portion of the information will be stored directly on the implanted internal system. To retrieve data, the handheld may be used to query the device and display on the screen data, such as the serial number, patient name, doctor's name, band size, fill volume, fill volume, and adjustment history.

As to the implant system's power source, although the above specifically mentions an implanted battery, the implant could be powered by a variety of internal power sources that meet the energy requirements such as the following: (a) kinetic energy creation by body

motion stored onto a capacitor; (b) an implanted fuel cell; (c) an implanted power source powered by chemistry of the body; (d) an implanted power source powered by temperature change; and (e) implanted batteries that can be recharged by direct contact. The handheld control device will typically be powered by rechargeable batteries while some embodiments may use other power sources. For example, a power cord may be supplied to allow recharging of the device in between uses with in most embodiments a fully charged device performing a day's worth of queries of a plurality of implanted band systems.

The self-regulating gastric band adjustment system of the present invention presents a number of design advantages. For example, the system provides precise and safe operation and supports telemetric communication with the implant. The system is configured so as to reduce risk of infections and to improve patient comfort. The implantable battery or power source provides a reliable and consistent power supply. The system can be operated to provide feedback on the state of the implant, which can be used for improving therapeutic intervention and patient follow-up.

In some embodiments, the external monitoring and control device, such as device 410 of Figure 4, is configured to control operation of the internal band adjustment system. In these embodiments, the sensor 450 (or the controller 432) is queried by the external device 410 via telemetry 426 to gather data on the parameter being monitored by the sensor at 452 and/or 456. Based on the current readings, the clinician or operator of the device 410 that is gathering this information can then change the monitoring limits (i.e., the band settings 438 that may be programmed into the sensor 450 when the sensor 450 is configured to intelligently monitor the operating bounds of the band 460) of the parameter such as to increase or decrease pressure or stress and strain of the gastric band. The sensor 450 (or controller 432 by storing new band settings 438) can then reprogrammed to read data and determine if the new data is within the modified control limits. The sensor 450 sends a signal to the control mechanism 432 to adjust the band 460 such that (or until) the sensor 450 reads data (i.e., a gastric band property or parameter) within the control limits (or band settings 420 or 438).

For example, a band may be monitoring or reading a band parameter (such as fluid pressure within the band 460) between 2 and 3 psi when the clinician queries the sensor 450

by operating the external device 410. The clinician, physician, or other operator may then choose to increase the monitoring range of the band to a range having 5 psi as its midpoint. The physician will re-program the sensor 450 to monitor between 4.5 to 5.5 psi (such as by resetting the band settings 420 and/or 438) and send this to the sensor 450 telemetrically 426. The sensor 450 resets its monitoring limits (or the controller 432 resets its band settings 438 for use in comparison of sensor-obtained band parameters) and communicates with the controller 432 to activate the implanted pump assembly 442 such that a volume of fluid is pumped into the band or out of the band until the sensor 450 reads (via 452, 456) within the control limits.

During operation, the pump draws power from the implanted battery or power supply 444 to allow for the adjustment and also activates any check valves to open (as discussed with reference to Figures 5-10). To inflate the band 460, the pump assembly 442 pulls fluid from the reservoir 446 into the band 460. To deflate the band 460, the pump assembly 442 pulls fluid from the band 460 back into the reservoir 446. Once the sensor 450 reads within the specified parameter range, appropriate check valves are closed to prevent fluid migration from or to the band 460. To confirm the new pressure (or other band parameter) reading, the clinician or operator uses the handheld 410 to query the sensor 450 for another reading. If confirmed, the pump assembly 442 and sensor 450 are shut off until queried again to conserve power.

Figures 5-10 illustrate particular self-regulating gastric band systems that may be employed to practice the invention. Each described system providing an alternative example of an effective pump assembly may be employed in a gastric band system (such as for the pump assemblies of internal band adjustment systems of Figures 1-4). The described systems each employ a pressure sensor for use in detecting or determining the fluid pressure in the inflatable or expandable portion of the gastric band (hereafter labeled "inner expandable ring"). However, it should be remembered that the invention is not limited to only a pressure sensor and that many embodiments of the invention (including those described in Figures 5-10 with a substitution of the sensor) employ other sensors for directly sensing one or more gastric band properties or physical parameters.

For example, but not as a limitation, the sensors employed may included:

1. Pressure Sensors, such as those available from CardioMems and Tronics Microsystem, SA;

2. Implantable grade stress-strain sensors, e.g., those available from CardioMems and Tronics Microsystem, SA or being developed by these companies individually or in joint efforts with Inamed (the assignee of this patent application);

3. Linear motion sensors, such as those available from Microstrain, Inc. (e.g., see http://www.microstrain.com/images/sensorman.jpg, which is incorporated herein by reference);

4. Distance sensors, such as those distributed by Microstrain, Inc., to measure the distance between two points;

5. Force sensors, such as those distributed by Microstrain, Inc., to measure the force exerted against an area by the saline;

6. Thermal sensors, such as those available or in development by Verichip or by Verichip and Inamed (the assignee of this patent application), to measure a thermal gradient from a low level heat source to approximate distance; and

7. Shell thickness gauge to detect reduction in shell wall thickness due to elongation during expansion.

Referring to Figure 5, a schematic of a self-regulating gastric band system 500 is illustrated includes a gastric band 510 for implanting in a patient in a circular configuration about their stomach to form a stoma. The band 510 includes an outer ring reservoir 512 for storing fluid for use in adjusting the size of the band 510, e.g., a lumen may be provided in outer ring or shell of the band that extends at least partially about the circumference of the band 510 (or along the band's length when it is not implanted or placed in its circular configuration such as from a head to a tail of the band or from a first end to a second end of the band). An inner expandable or inflatable ring 514 is provided in the band 510 that is formed of a material that allows it to expand as it received a fluid and to deflate or contract when the fluid is removed or drained.

As discussed above, expandable gastric bands are well known in the art, and nearly any of these known bands may be employed in the system 500 with modifications to include

the outer ring reservoir 512 and a fluid connection line 517 (or reservoir fill/drain line or tube) provided to the reservoir 512. During use, the inner expandable ring 514 is filled and drained of fluid via a fill line or tube 516 (which more accurately may be considered a band size adjustment line). Initial sizing of the band 510 is performed via access or manual port 518 that is typically implanted just beneath the patient's skin and which is connected to the fill line 516. Sizing includes a clinician injecting a volume of fluid that is typically selected for the gastric band 510 in an attempt to obtain a desired inner diameter of the band 510. Fine tuning and ongoing "self-regulation" is performed in the system 500 using an internal band adjustment system made up of a pump assembly 530, a sensor 522, a power supply 528 (e.g., one or more batteries), and control and communications components. Although not shown, the system 500 may interact with an external monitor/control device as discussed in detail above. In this regard, an antenna or other wireless communication component 524 is provided in the internal assembly and linked to the control 526, and this antenna 524 allows telemetry to be used to communicate band parameters and other information (again, as discussed in detail above) with the external monitoring/control device.

As illustrated, a housing 520 is provided such that the components of internal band adjustment system can be isolated within the patient. Within the housing 520, a pump assembly 530 is provided along with the sensor 522, the antenna 524, a control 526, a battery or power source 528, and memory 529 (which may be incorporated in the sensor 522 and/or control 526). The sensor 522, control 526, battery 528, and memory 529 provide the functionalities described in detail with reference to Figure 4 and the preceding description. In this embodiment, the sensor 522 is a pressure sensor for sensing the fluid pressure in the inner expandable ring 514. To this end, the fill line 516 is routed to the housing 520 from the access or manual port 518 through or via contact with the sensor 522 to the inlet of the inner expandable ring 514. In some embodiments, the sensor 522 includes a pressure transducer that can sense directly the back pressure applied by fluid in the inner expandable ring 514 on fluid in the fill line 516. In other embodiments, the sensor 522 or a portion of the sensor 522 is provided in the band 510 such as in or near the inlet port to the inner expandable ring 514 for the fill line 516 or interior to the inner expandable ring 514.

The sensor 522 may be inactive for periods and be activated by the control 526, by an internal timing mechanism, and/or by an external monitoring device. The sensor 522

when activated takes pressure readings and provides these to the control 526 for storage in memory 529 and/or for comparison against a preset operating range (i.e., minimum and maximum pressure limits or bounds such as 3 to 7 psi or more likely 4 to 5 psi, which may be considered band settings) stored in memory 529. Alternatively, the sensor 522 may have intelligence and memory and act to compare the read pressure readings (i.e., directly obtained band property) to band settings programmed into the sensor 522. When the read pressure in the band 510 is outside the band settings, the sensor 522 may awaken the controller 526 to operate to raise or lower the pressure in the band 510 by operating the pump assembly 530 to add or withdraw fluid from the inner expandable ring 514. The battery 528 provides a local power source for power consuming components within the housing 520 such as the control 526, the sensor 522, and any pumps and/or electronic valves in the pump assembly 530. In addition to band settings, the memory 529 may pressure readings from the sensor 522 and other data related to the gastric band 510 (such as the band identification information, the date of implantation, and the like) as well as, in some cases, data related to the patient (such as patient name, last treatment date/time, and the like).

The pump assembly 530 functions generally to respond to control signals from the control 526 to either pump fluid into the inner expandable ring 514 or to remove or withdraw fluid from the inner expandable ring 514 to thereby size the band 510, whereby a band parameter or property monitored by the sensor 522 is returned to within an operating range or to within band settings. As shown, the pump assembly 530 of system 500 includes a bleed valve 532 (e.g., a ceramic bleed valve or the like operated by a spring plunger) in fluid communication with the outer ring reservoir 512 via line 517. The bleed valve 532 is operated by a pump 534 (e.g., a 7 psi Bartel actuator pump or other pump having the same capacity or a larger or smaller capacity or pressure rating) that is primed with an internal reservoir 536. The bleed valve 532 is also shown to be connected to the fill/drain line 516 of the inner expandable ring 514. The bleed valve 532 is provided to allow the pump assembly 530 to equalize the pressure between the outer ring reservoir 512 and the inner expandable ring 514, which may be desirable in some embodiments (and when not, these components associated with the bleed valve 532 may be omitted from pump assembly 530).

Further (or alternatively), the bleed valve 532 may be used to drain/withdraw fluid from the inner expandable ring 514. In these embodiments, the sensor 522 may sense a

pressure that is too high, i.e., above an upper limit of a band setting or operation range, and the control 526 may respond to a signal from the sensor 522 to activate the pump 534 to open the bleed valve 532. A pressure differential between the outer ring reservoir 512 and inner expandable ring 514 results in flow of fluid from the inner ring 514 via fill line 516 and bleed valve 532 to the outer ring reservoir 512 (e.g., this operational embodiment assumes the fluid reservoir 514 is maintained at a lower pressure than fluid in the inner expandable ring 512). The sensor 522 continues to monitor the pressure in the inner expandable ring 512 and when it (or the control 526) determines that the pressure is within the desired operating range (or more typically at or near the center or midpoint of such a range) the control 526 is operated to deactivate the pump 534 to shut the bleed valve 532.

The pump assembly 530 of system 500 also includes a pair of check valves 542, 546 (e.g., Bartel micro check valves or the like) between which is positioned a pump 540 (e.g., a 20-psi Bartel custom actuator pump or the like). One check valve 542 is connected to the outer ring reservoir 512 via line 517, and one check valve 546 is connected to the inner expandable ring 514 via fill line 516. The pump 540 is connected between the check valves 542, 546 with flow during pumping to be from the outer ring reservoir 512 to the inner expandable ring 514. With this arrangement, the pump 540 can be used to increase the size of the band 510 when operated by the control 526 to pump fluid from the outer ring reservoir 512 through the check valves 542, 546 into the inner expandable ring 514. The control 526 provides a shut off signal when the pressure of the fluid in the inner expandable ring 514 is within the set operating range (or at or near a midpoint or other preset point within such a range) as determined by operation of the sensor 522 and control 526.

In some cases, the band 510 may be adjusted to have a smaller size by withdrawing fluid from the inner expandable ring 514 via the pump 540. In these embodiments, the sensor 522 may sense a pressure that is too low (i.e., less than a lower bound or limit of the operating range or band parameters) and provide this information to the control 526. The control 526 then signals the check valves 542, 546 to open and fluid is allowed to flow backwards through the pump 540 to the outer ring reservoir 512 via line 517. This embodiment also assumes that the pressure of the outer ring reservoir 512 is less than that of the fluid in the inner expandable ring 514, and that the pump 540 is configured to allow back flow when it is not actively pumping. When the sensor 522 senses a pressure within the

programmed operating range (or a midpoint or other set point within that range) as determined by the sensor 522 and/or the control 526, the control 526 operates to close check valves 542, 546.

Figure 6 illustrates one physical arrangement for the pump assembly 530. As shown, the housing 520 is a one-piece unit or box that encloses the sensor 522, the control 526, the battery 528, the pumps 534, 540, and internal reservoir 536 (as well as other components of the pump assembly 530). The housing also provides fluid ports or connection points for the fill line 516 and reservoir connection line 517. The materials used for the housing 520 are preferably biocompatible, and the housing 520 is preferably constructed to be leak resistant (e.g., water or fluid "tight") to support extended use of the pump assembly as an implant. In other embodiments not shown, the housing 520 may take different shapes such as a cylinder, a square, or other useful shape and may be modular such that differing components are provided in two or more enclosures that may be attached or provided as detached modules.

Figure 7 illustrates a schematic of another embodiment of a self-regulating gastric band system 700. The system 700 is configured similarly to that of system 500 with an adjustable gastric band 510 having an inner expandable ring 514 and an outer ring reservoir 516 that with fill/drain lines 516 and 518, respectively. An access port 518 is connected to the fill/drain line 516 to allow external filling of the inner expandable ring 514 with saline or other fluid, such as during the implant process to initially size the band 510. In a housing 720, a sensor 722 is provided in fill/drain line 516 to sense the fluid pressure of the gastric band 510 in the inner expandable ring 514. An antenna 724, a control 726, a battery 728, and memory 729 are provided with functionality similar to that of like components in system 500.

The system 700 differs from the system 500 in the configuration of the pump assembly 730 provided as part of the internal band adjustment system in housing 720. As shown, the pump assembly 730 includes a bleed valve 732 connected to the fill/drain lines 516, 517 that is operated similarly to valve 532 by operation of the pump 734 and reservoir 736 and control 726. However, the pump assembly 730 differs from pump assembly 530 with replacement of a single pump 540 with a plurality of pumps 740, 742, 744 (e.g., three 7-psi Bartel actuator pumps or other pump useful for this function/purpose) that are arranged

in series between check valves 746, 748. The pumps 740, 742, 744 are operated via battery 728 and control 726 to pump fluid from the outer ring reservoir 512 into inner expandable ring 514 when the sensor 722 detects a pressure lower than a preset lower pressure limit. Further, in some embodiments, the check valves 746, 748 are opened by control 726 and powered by battery 728 to allow fluid in inner expandable ring that is under a pressure above a present upper pressure limit (as detected by sensor 722) to flow out of the inner expandable ring 514 through the pumps 740, 742, 744 into the outer ring reservoir 512 until determined by sensor 722 and control 726 to be within the preset operating range.

Figure 8 illustrates an embodiment of a self-regulating gastric band system 800 is similar to systems 500 and 700 including an expandable gastric band 510 with a self-contained fluid reservoir 512 and within housing 820 a pressure sensor 822, a communication module 824, a controller 826, a local power supply 828, and memory 829. The system 800 however includes a pump assembly 830 in the housing 820 that differs from the pump assemblies 530, 730. As shown, an optional bleed valve 832 is provided between the outer ring reservoir and the inner expandable ring 514 that is operable to maintain a desired pressure differential between the fluid in these two portions of the band 510 (or system 800). For example, it may be desirable in some bands 510 to maintain a differential of less than about 2 psi or less than about 0.25 to 1 psi or the like. In other embodiments (not shown) of system 800, the bleed valve 832 may be omitted.

To allow for selective adjustment of the size of the inner expandable ring 514, the pump assembly 830 includes a pair of check valves 846, 848 connected to the fill/drain lines 516, 517. Pumping or fluid motive forces are provided by a syringe or other chamber 842 that is in fluid communication with the two check valves 516, 517 and therefore, with the two reservoirs or portions 512, 514 of the band 510. Fluid is drawn into and forced out of the chamber 842 by operation of a squiggle motor 838 that is sealed in a motor casing 834 having a bellows 836 to support movement of a shaft/plunger 840 connected to the motor 838 (e.g., a Squiggle motor or the like) and chamber 842.

During operation of the system 800, the sensor 822 senses pressure in the inner expandable ring 514 of the band 510. The sensed or monitored band property is either used by the sensor 822 to determine if the band pressure is within a programmed or preset

operating range or such a determination is made by control 826. Once a determination is made that the pressure is lower than a preset lower limit or out of range low, the control 826 operates the motor 838 to pump fluid from the outer ring reservoir 512 into the inner expandable ring 514 via check valves 846, 848 and fill/drain lines 516, 517 until the pressure in the band 510 as sensed by sensor 822 is within the preset operating range (or typically some amount higher than the lower limit). When a determination is made that the pressure of fluid in the inner expandable ring 514 is higher than a preset upper limit or out of range high, the control 826 may adjust the pressure (and corresponding size of the ring 514) by opening check valves 846 and 848 to allow fluid at a higher pressure in the inner expandable ring 514 to flow to the outer ring reservoir 512 via fill/drain lines 516, 517 until the pressure detected by the sensor 822 is again within the range (or at a pressure a preset amount below the upper pressure limit).

Figure 9 illustrates another self-regulating gastric band system 900 similar to the systems 500, 700, and 800 in that it includes a gastric band 510 and a housing 920 that encloses a pressure sensor 922 in the fill line 516 of the band 510, an antenna or communication element 924, a control device 926, a battery 928, and memory 929. The pump assembly 930 is similar to assembly 830 in that it includes a bleed valve 932 in fluid communication with the inner expandable ring 514 and outer ring reservoir 512 via lines 516, 517 for maintaining a desired pressure differential between the two lumens or reservoirs 512, 514. The pump assembly 930 differs from assembly 830 in with the insertion between check valves 942, 946 of a pumping mechanism that is made up of a motor casing 934 sealing a squiggle motor 940 that is used to drive or move a diaphragm 938 via a shaft extending through or into bellows 936. Other operations of the system 900 are similar to that of system 800.

Figure 10 illustrates a self-regulating gastric band assembly 1000 that is configured similar to system 500 of Figure 5. Differences between the systems (or unique aspects of system 1000) include the positioning of the sensor 1022 external to the housing 1020 between the inner expandable ring 514 and a check valve 1049 in the fill line 516. The sensor 1022 is in communication (wired or wireless) with the controller 1026, which acts to communicate with an external monitoring/control device (not shown in Figure 10) via antenna or communication element 1024, to store data received from sensor 1022 and

external monitoring/control device in memory 1029, and to power the pump assembly 1030 (as needed) with battery 1028, which also powers the controller 1026. The controller 1026 is also configured to operate (as discussed in detail above) the pump assembly 1030 to automatically maintain the band 510 within a desired operating range typically defined by a lower and an upper limit (e.g., a lower pressure limit and an upper pressure limit) by pumping fluid into and out of the inner expandable ring 514 based on band properties sensed by sensor 1022 (e.g., pressure of fluid in line 516 and in ring 514).

The system 1000 also differs from system 500 in the configuration of its pump assembly 1030. The pump assembly 1030 includes a bleed valve 1032 for bleeding higher pressure fluid in the inner expandable ring 514 (when sensed by the sensor and based on control signals from the control 1026) to the outer ring reservoir 512. The assembly 1030 however includes a different pump 1034, e.g., a 5-psi Thinxxs pump or the like, than that used in the system 530, that is primed by internal reservoir 1036 to operate the bleed valve 1032 in response to signals from the control 1026. The system 1000 further differs from system 500 in that a plurality of pumps 1040, 1042, 1044, 1046 (e.g., 5-psi Thinxxs pumps or other useful pumps) are positioned between check valves 1048, 1049 and the reservoir 512 and inner expandable ring 514 rather than a single pump 540. These serially-arranged pumps 1040, 1042, 1044, 1046 are operated to pump fluid from the reservoir 512 into the inner expandable ring 514 when the senor 1022 detects a pressure below (or outside low) a minimum pressure defining a lower bound of the desired operating range or the programmed pressure range for the band 510.

As can be seen from Figure 5-10, there are many different pump assembly configurations that may be used to implement the present invention. Additionally, other components may be varied to achieve the desired functionality of a self-regulating gastric band. For example, the systems shown in Figures 5-10 included a fluid reservoir provided in a lumen or integral portion of the gastric band. In some embodiments, it may be desirable to have the fluid reservoir be provided within the pump housing. In other cases, the fluid reservoir may be provided as a component external to the pump housing and external to the gastric band, such as by providing a separate elastic sack, balloon, or other similar structure that would be useful for storing fluid for pumping into the band and out of the band by the pump assembly.

In some embodiments, it is desirable to allow adjustment of an implanted band by a physician or other technician via a telephone link. Briefly, this is achieved by providing a controller local to the patient and a remote controller local to the physician or technician, with the two controllers communicating via a wired and/or wireless telephone link. The local controller can be thought of as a remotely adjustable band (RAB) handheld controller (or the controller can be fixed but local to the patient) or RHC. The primary function of the RHC is to: locate the implanted pump, control the implanted pump, provide an easy to use programming and system status display, allow access to the RHC functions through remote dialup, provide a web server application which allows for web page-based control of all functions when accessed through remote dial up, and provide a standard wireless link to a cradle, which provides charging power to the controller and a telephony link (for accessing the web page and/or other controller). The local controller or RHC may, for example, be used to communicate via the antennae of the systems shown in Figures 1-10, and the use of such an RHC is explained in more detail in the following description.

Figure 11 illustrates in functional block form a gastric band system 1100 that uses a RAB controller 1150 to control adjustments of an implanted (or implantable) band 1190. Figure 12 illustrates RAB controller 1150 and its cradle 1110 in more detail. As shown, the system 1100 includes a cradle 1100 for providing telephony connections and power for a RAB handheld controller or RHC 1150. The RHC 1150 in turn is used to control via transferred data over wireless link 1162 an implanted pump 1170, which adjusts or regulates the size of a gastric band 1190 by controlling fluid transfer over connection 1179. Fluid is supplied in this example by external reservoir 1180 (e.g., external to a housing of the pump assembly 1170 or via a manual port 1184 (e.g., for an initial filling or sizing of the ban 1190) via connections 1181, 1185. As with previously described pump assemblies, the pump assembly 1170 includes telemetry circuitry 1172, controller and memory 1174 and one or more hydraulic pumps 1178.

The RHC 1150 is shown to include a user interface 1152 and display 1154 along with a keypad (or user input mechanism) 1164 to allow a user (such as gastric band patient or other operator of the system 1100) to view data from the pump assembly 1170 and data received remotely via the telephone link 1118 and to allow the user to make adjustments and enter data in some cases. The RHC 1150 further includes a system controller 1156, a

wireless circuitry and antenna or cradle link 1158 for communicating with the cradle 1110, an implant telemetry 1160 for communicating with the telemetry circuitry 1172 of the implanted pump assembly 1170, and a power supply/battery 1168 to allow the RHC 1150 to be used outside the cradle 1110.

The cradle 1110 provides a power link 1128 by providing a power link 115 to a power supply 1104 via power supply 1120 and RHC charger 1126. More significantly, the cradle 1110 includes a controller 1111 and a telephone/data link 1118 to facilitate remote control of the RHC 1150 and pump assembly 1170 via a telephone jack or other connection 110 that is linked 1103 with a line interface 1112 to communicate with the RHC 1150 via wireless communication circuit/antenna 1114. The primary functions of the RHC cradle 1110 are to: charge the RHC battery 1168, store the RHC 1150 when not in use, provide telephone/line interface including a modem (in some cases as shown in Figure 12) for data access via interface 1112, implement a standard wireless data link 1118 between the modem and RHC 1150 to allow remote access to the RHC features and pump assembly 1170, and allow access to the RHC functions through remote dialup.

Figures 13 and 14 illustrate one useful physical implementation of the RHC 1150 and the cradle 1110. These figures show that the RHC 1150 can easily be removed and inserted or docked into the cradle for charging via power connection (or docking connector) 1128. A telephone line 1103 is connected to (or connectable to) cradle 1110 as is a power line 1105 (such as a 12 volt direct current line). The display 1154 upon which a user interface 1152 would be provided is shown in the RHC 1150 as is a keypad 1164 and a power on/off switch or button 1356. The RHC 1150 may be configured in a number of ways to include the implant telemetry access antenna and standard wireless antenna 1156, 1160 with these shown in Figure 14 to be provided on the rear of the body or housing of the RHC 1150 for ease of access and maintenance. As can be seen, the RHC 1150 is configured for easy handheld operation to allow a user to place the RHC 1150 near the patient and the gastric band 1190 to facilitate communications with implant telemetry circuitry 1172 in the pump assembly 1170 and ease of data input/output via display 1154.

It may now be useful to discuss a few of the operational features of the system 1100 and RHC 1150 along with a discussion of its operations, with reference to Figure 15, to

regulate an implanted gastric band 1190. The useful features of the system 1110 and the RHC 1150 include: (a) the implantable pump 1170 that the RHC 1150 controls is self-powered and does not require power to be transferred by the controller 1150; (b) the implantable pump 1170 performs adjustments to the band 1190 until a desired band pressure is achieved (as opposed to a desired volume); (c) the RHC 1150 contains a standard wireless interface 1158, such as Bluetooth or ZIGBEE, connecting the RHC 1150 to the telephony interface 1114 in the RAB cradle 1110 which in turn connects via interface 1112 and connection 1103 to a remote computer or controller (not shown) capable of performing a dial-up access or otherwise communicating data and control information to the RHC 1150; (d) the RHC 1150 contains networking software run by controller 1156 allowing connectivity from remote computers through the telephone interface provided by cradle 1110 and wireless interface 1158; (e) the RHC 1150 contains a web server run by system controller 1156 allowing web-based access to all RHC 1150 functions, including adjustment commands, after a dial up networking connection has been established over the telephone interface, which eliminates the need for installing application specific software on accessing computer (e.g., in one embodiment, Secure Internet Explorer or a similar connection is the utilized).

The RHC 1150 operates in the following high level modes: normal, remote accessed, docked, and powered down. Figure 15 illustrates operation of the RHC 1150 (or gastric band system 1100) in the normal mode for remotely adjusting or regulating 1500 a gastric band in a patient. In this mode the RHC's primary function is to access and control the RAB implantable pump 1170. Wireless access to the implantable pump 1170 may be, for example, through the Medical Implant Communications Service (MICS) band operating in the 402-405 MHz frequency range. The communication protocol between the RHC 1150 and implantable pump 1170 may be kept compliant with patient privacy regulations and health industry regulations. The flow chart of Figure 15 shows a typical set of activities leading to an adjustment. Adjustments are typically in the form of pressure changes in the band as opposed to discrete volumetric change.

In the normal regulation mode or process 1500, the RHC 1550 is powered on at 1510, such as by pressing a button or moving a switch 1356 on the RHC 1550. At 1520, a password entry may be required to use the RHC 1550 to prevent unauthorized users from

adjusting the band 1190. At 1530, the RHC 1550 is operated by the system controller 1156 to search and find the implanted pump 1170 such as communications being performed between the implant telemetry 1160 in the RHC 1150 and the telemetry circuitry 1172 of the pump assembly 1170 with the link 1162 being established at 1540 when the assembly 1170 is found by the RHC 1150. At 1550, the RHC 1550 acts to retrieve and display data that is stored in the memory 1174 of the implanted pump assembly 1170.

At 1560, the RHC 1550 prompts via UI 1152 and display 1154 for a pressure change input (i.e., does the user wish to change or adjust the pressure in the gastric band 1190 to adjust the band 1190). At 1570, input has been received (such as via input by the user via keypad 1164 and/or UI 1152) and a pressure change command(s) is sent via link 1162 from the RHC 1150 to the implanted pump assembly 1170. At 1580, the RHC 1550 waits for a confirmation from the implanted pump assembly 1170 that it has completed the pressure change in the gastric band 1190 (e.g., via operation of the pump 1178 by the controller 1174 to add or remove fluid via connections 1179, 1181 and fluid reservoir 1180 as discussed in detail with reference to Figures 1-10). The process 1500 may then continue with retrieval of additional data at 1550 or more typically, with displaying a confirmation and then prompting for input of additional changes at 1560.

An innovative feature of the system 1100 (and the systems of Figures 1-10) is the capability for a physician to perform remote band adjustment. By operating the system 1100, physicians or other operators are able to connect securely from their office computers to the RHC 1150. This connection and control communications are achieved by operating the physician's or other operator's computer to "dial-up' and connect to the RAB system 1100 through a telephone modem or link in the cradle 1110.

The following sequence of events occur in one embodiment to achieve remote access to and control of the RAB system: (a) the patient connects the cradle 1110 to an active telephone jack 1102 using a standard telephone cord 1103, with the physician typically being made aware of the phone number of the cradle/jack prior to attempting the remote access; (b) the physician uses standard windows dial-up networking software to dial the RAB system 1100; (c) the cradle 1110 contains the telephone interface and modem circuitry 1112, and upon detection of a telephone ring signal on the telephone line 1103, the cradle 1110

automatically "picks up" and the modem 1112 is activated; (d) the modem 1112 in the cradle 1110 establishes a connection 1103 with the physician's computer modem (not shown); (e) the cradle 1110 then establishes a wireless data link 1118 between the modem or interface 1114 and the RAB Handheld Controller 1150, which contains networking software (e.g., a TCP/IP stack run by system controller 1156 and/or with wireless interface 1158); (f) the RHC 1150 establishes a network connection with the physician's computer, with the connection typically being encrypted and compatible with Microsoft Internet Explorer secure connection or the like; (g) the physician launches the Microsoft Internet Explorer or similar application on their computer or other remote controller and, using a predefined web address, gains access to a web based application on the RHC 1150 allowing full control of the RHC's function; (h) the physician performs all functions allowed in the normal mode of operation (e.g., method 1500 of Figure 15) after entering the appropriate access codes (Username and/or password); and (i) the patient or operator of the RHC 1150 will be prompted on the RHC screen or display 1154 on what action they should take to facilitate remote adjustment/control of implanted pump assembly 1170 by the physician. In many cases, the wireless data link will be either Bluetooth, ZIGBEE, or other communication protocol/technique compliant.

The docked mode of operation is primarily used for charging the RHC 1150. However, remote access may be provided for the purpose of preprogramming an adjustment or retrieving patient data. In the powered down mode of operation, the RHC functions are suspended except for battery charging and charge monitoring.

The operation of a self-regulating gastric band system has been described in detail with reference to Figures 1-15, but it may be useful to provide yet another summary of an embodiment of such a system. An implantable pump assembly is provided that allows for a non-invasive pressure management of an implantable gastric band, and this function is typically invoked as a response to commands transmitted from the RAB Handheld Controller (RHC) shown in Figures 11-15 or other controller. The implanted pump assembly and its components are internally powered (i.e., powered locally by a battery or the like rather than remotely or external to the patient's body).

The implanted components (or internal band adjustment system) include the following functional components: an enclosure; an external reservoir; a manual port; a fluid pump (e.g., a Bartels 20 PSI pump with active valve or the like); a control circuitry (e.g., for controlling the pump and any valves); telemetry circuitry and antenna; and a battery and power supply circuitry. The RAB implantable pump can be implemented as a piezoelectric 20 PSI (or other capacity) pump, e.g., a pump with an active valve incorporated into its design. The implantable pump is preferably self-powered through a custom implantable battery designed for long term implantation. The pump has inlet and outlet valves. For a robust design, check valves at the pump inlet and the pump outlet are used to eliminate or control leakage, such as micro check valves. For pressure release and pressure equalization, the system may use a piezoelectric or active valve or the like. The system directly pumps fluid from the reservoir to the band, changing the band pressure. Band pressure release is accomplished through a separate sub-system. Increase in pressure in the band is done directly via the pump. Decrease in pressure is achieved through pressure release followed by re-pumping the band to the proper pressure.

The following describes the two modes of band adjustment. In normal operation, a 20-psi pump with 30-psi minimum back pressure withstanding check valve maintains directional flow between an external Reservoir and the gastric Band. The pump, e.g., a 20-psi piezoelectric pump or the like, is for pressure increase in the band and is monitored by a pressure sensor. Because of the nature of the piezo material, the flow is not reversible for pressure relief in the band. Pressure is maintained in the band once the pump is shut down. No leakage or back-flow occurs because of check valves that are integrated into the pump or provided separately.

To provide pressure relief/equalization, for pressure relief in the band, an active valve/flow re-direction mechanism, e.g., a piezo-active valve, is used. The active valve is opened to equalize pressure between the band and the reservoir. Once equalization is achieved, the active valve is shut down. The main pump is then activated to increase the pressure to the desired pressure in the gastric band.

Although the invention has been described and illustrated with a certain degree of particularity, it is understood that the present disclosure has been made only by way of

example, and that numerous changes in the combination and arrangement of parts can be resorted to by those skilled in the art without departing from the spirit and scope of the invention, as hereinafter claimed. To practice the invention, the gastric bands that are adjusted by the internal band adjustment systems of the invention may be external to the stomach as shown in Figure 1, for example, or may be provided or implanted internal to the stomach and/or esophagus, i.e., the gastric bands regulated according to the invention may be intragastric bands. Such an intragastric band may take the same or similar form of the bands described with reference to Figures 1-10 or another form (such as forms described in the following incorporated reference), and for example, may be attached and/or implanted in a number of ways such as shown in U.S. Pat. Appl. Publ. No. 2005/0192601, which is incorporated herein by reference.

CLAIMS

I CLAIM:

1. A self-regulating gastric band apparatus for adjusting stoma size, comprising:

a gastric band for placement in a patient to engage the esophagus and/or the stomach of the patient, the gastric band having an expandable inner portion with a lumen for receiving a fluid; and

a band adjustment assembly for placement in the patient proximal the gastric band, the band adjustment assembly comprising:

a sensor sensing a property of the gastric band;

a pump assembly in fluid communication with the lumen of the expandable inner portion; and

a controller operating the pump assembly to adjust a volume of the fluid in the lumen based on the gastric band property sensed by the sensor.

2. The apparatus of claim 1, wherein the sensor comprises a pressure sensor sensing pressure of the fluid in the lumen of the expandable inner portion.

3. The apparatus of claim 2, wherein the controller operates the pump assembly to increase the volume of the fluid in the lumen when the sensed fluid pressure is below a lower pressure boundary value and to decrease the volume of the fluid in the lumen when the sensed fluid pressure is above an upper pressure boundary value.

4. The apparatus of claim 3, wherein the band adjustment assembly comprises memory for storing the lower and upper pressure boundary values, wherein the controller or the sensor operate to determine whether the sensed fluid pressure is between about the lower pressure boundary value and the upper pressure boundary, and wherein the pump assembly is operated by the controller until the pressure is determined to be at a preset point between the boundary values.

5. The apparatus of claim 3, further comprising a communication module for receiving from a monitoring device external to the patient command signals, wherein the command signals comprise at least one of a new lower pressure boundary value or a new

upper pressure boundary value, and wherein the new boundary values are stored in the memory for use by the controller or the sensor in processing a next sensed fluid pressure.

6. The apparatus of claim 5, wherein the controller operates to retrieve information stored in the memory including the stored lower and upper pressure boundary values and other data relating to the gastric band or the patient and to transmit the retrieved information via the communication module to the external monitoring device in response to a query communication from the external monitoring device.

7. The apparatus of claim 1, further comprising a fluid reservoir for implanting in the patient configured for storing a volume of the fluid for use in the adjusting of the volume of fluid in the lumen, the fluid reservoir being in fluid communication with the pump assembly.

8. The apparatus of claim 7, wherein the fluid reservoir is provided in an enclosed lumen in the gastric band or in tubing associated with the band adjustment assembly.

9. The apparatus of claim 1, wherein sensor operates periodically to perform the sensing of the property and operates in response to a control signal from the controller or an external monitoring device to perform the sensing of the property.

10. The apparatus of claim 1, further comprising a local controller communicating with the band adjustment assembly controller to provide command signals to operate the pump assembly and to retrieve information gathered by the band adjustment assembly controller, wherein the local controller is configured for providing a communication link with a remote controller mechanism to receive the command signals and to transfer at least a portion of the retrieved information to the remote controller mechanism.

11. The apparatus of claim 10, wherein the communication link is a wireless data transfer link and wherein the apparatus further comprises a cradle linkable to a telephony system and providing the wireless data transfer link, whereby the local controller communicates with the remote controller mechanism via the wireless data transfer link and the telephony system via the cradle.

12. A self-regulating gastric band system, comprising:

a gastric band for engaging a patient's stomach, the gastric band having a expandable portion with a cavity that has a volume varying with an amount of fluid in the cavity;

means for sensing a physical parameter associated with the expandable portion; and

means for adjusting the volume of the fluid in the cavity, the adjusting means comprising means for determining when the sensed physical parameter is outside of an operating range for the physical parameter and when determined outside for increasing or decreasing the volume of the fluid until the sensor senses the physical parameter is within the operating range.

13. The system of claim 12, the adjusting means comprising memory for storing a lower bound and an upper bound defining the operating range and a reset point and comprising a pump selectively operable to pump additional amounts of the fluid into the cavity of the expandable portion until the sensing means senses the physical parameter is a value of about the reset point.

14. The system of claim 13, wherein the sensing means comprises a pressure sensor positioned to sense a pressure of the fluid in the cavity and wherein the lower and upper bounds and the reset point are pressure values.

15. The system of claim 12, the adjusting means comprising a power source, a controller, a fluid reservoir, a pump in fluid communication with the fluid reservoir and the cavity, and at least one check valve in fluid communication with the pump and the cavity, wherein the controller operates the pump powered by the power source to pump fluid from the fluid reservoir into the cavity to perform the increasing of the volume of the fluid in the cavity and operates the at least one check valve to open to perform the decreasing of the volume of the fluid in the cavity.

16. The system of claim 15, further comprising a housing formed of biocompatible material with liquid resistant walls enclosing the adjusting means and the sensing means.

17. The system of claim 12, further comprising a means for wirelessly communicating with the adjusting means to retrieve the sensed physical parameter, to retrieve the operating range for the physical parameter, and to modify the operating range.

18. The system of claim 12, wherein the gastric band further comprises a shell defining a fluid reservoir storing fluid and wherein the adjustment means comprises means for transferring fluid between the fluid reservoir and the cavity in the expandable portion to increase or decrease the volume of the cavity.

19. A method for treating obesity by adjustable gastric banding, comprising:

placing in a patient's body a self-regulating gastric band assembly comprising a gastric band with an expandable inner ring engaging the patient's stomach and/or esophagus to form a stoma and comprising a band adjustment system in a biocompatible enclosure; and

setting an operating range for a property of the gastric band;

wherein the band adjustment system operates without operator intervention for:

sensing the property of the gastric band;

comparing the sensed property of the gastric band with the operating range; and

based on the comparing, adjusting a volume of fluid in the expandable inner ring such that the property of the gastric band is within the operating range.

20. The method of claim 19, wherein band adjustment system comprises a sensor, a pump assembly, and a controller and wherein the sensing is performed by the sensor, the comparing of the sensed property is performed by the sensor or the controller, and the operating of the band adjustment system comprises transmitting signals from the controller to the pump assembly.

21. The method of claim 20, wherein the gastric band comprises an outer ring defining a fluid reservoir and wherein the pump assembly is in fluid communication with the fluid reservoir and the expandable inner ring and the pump assembly transfers fluid from the fluid reservoir to the expandable inner ring and transfers fluid from the expandable inner ring to the fluid reservoir based on the signals from the controller.

22. The method of claim 20, wherein the band adjustment system further comprises means for wirelessly communicating with a device external to the patient's abdomen and comprises memory storing an upper and a lower limit defining the operating range, the method further comprising operating the external device to retrieve from the memory the limits via the communicating means and to modify at least one of the limits stored in the memory.

23. The method of claim 22, wherein the external device comprises a pair of controllers and the method further comprises communicating in a wired and/or wireless fashion to exchange the limits and other information collected from the memory and command signals for use in the operating step to perform the modifying of the at least one of the limits stored in the memory.

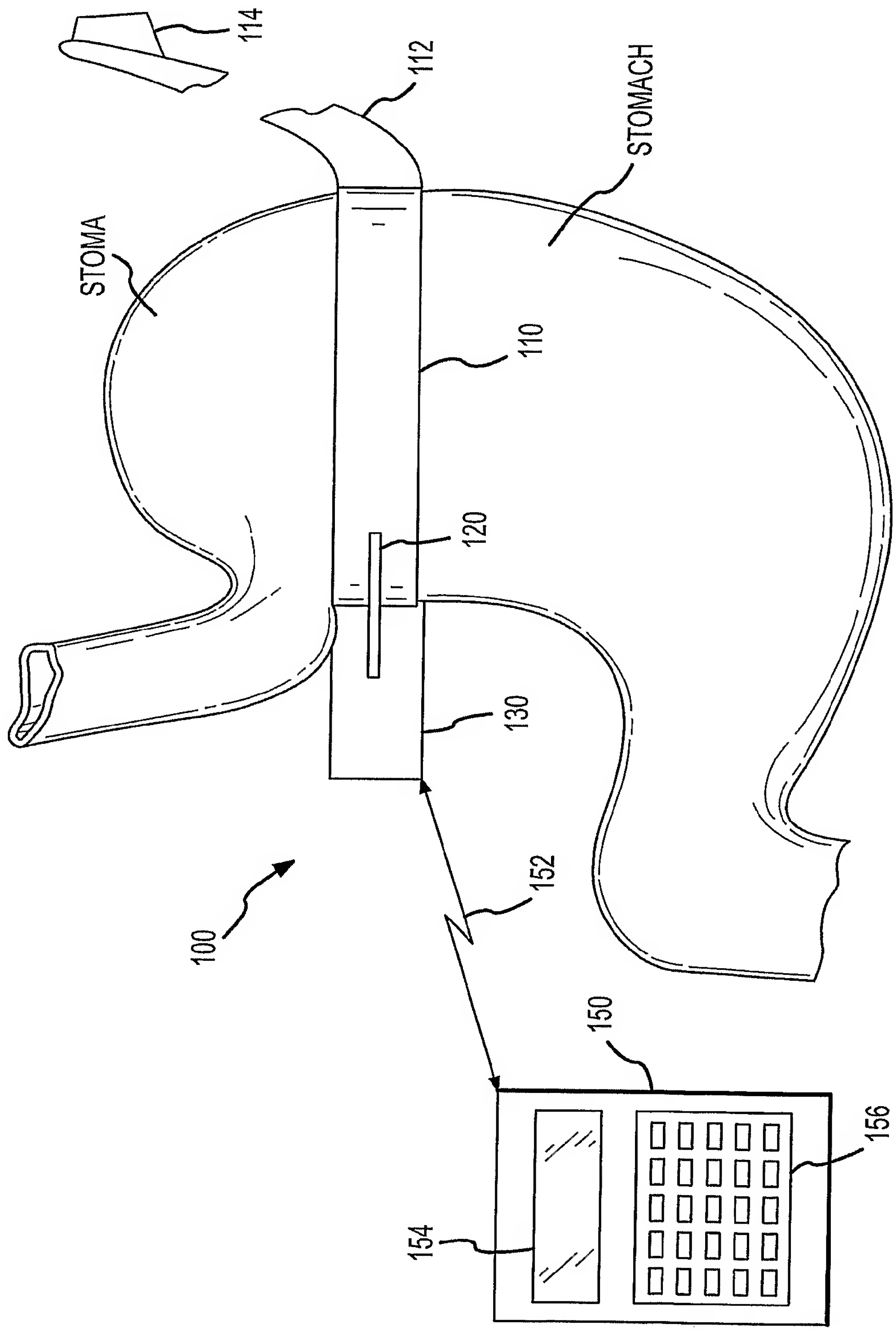


FIG.1

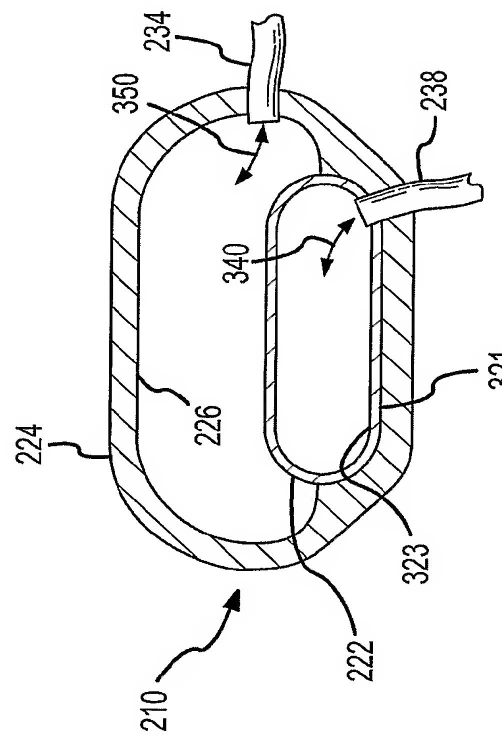

234
350
238
340
321
224
226
323
210
222

FIG.3

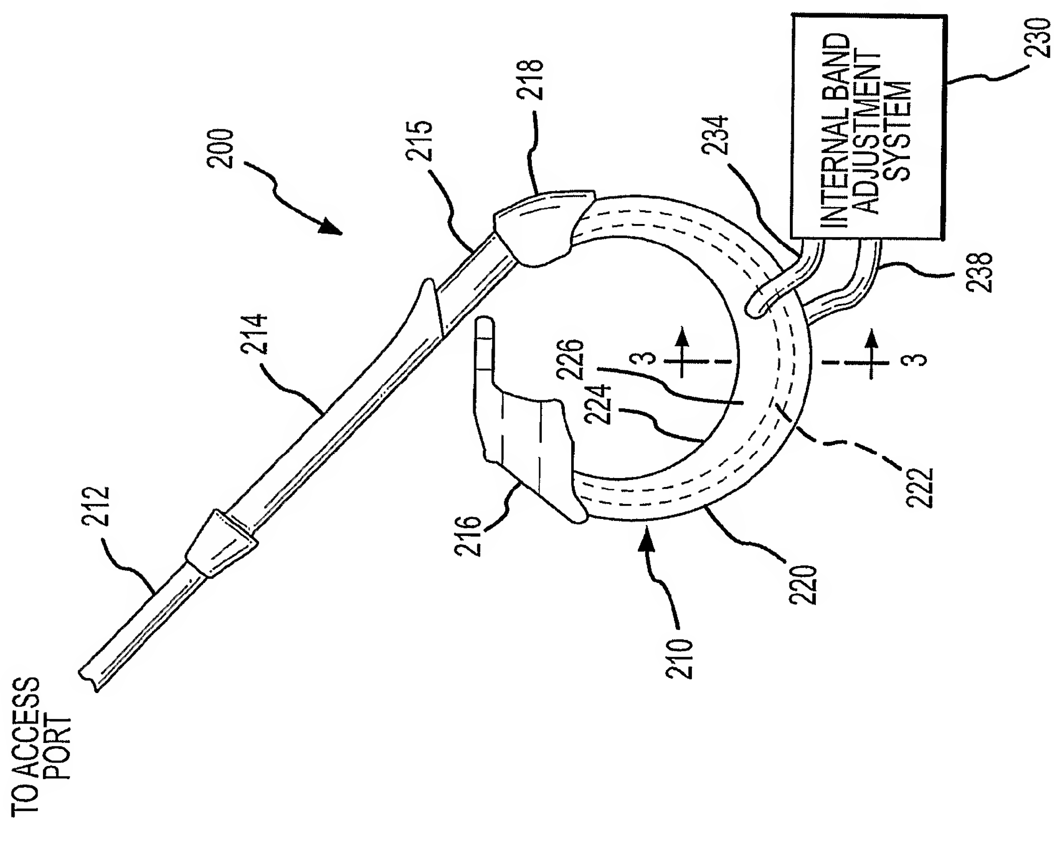

200
215
218
214
234
230
INTERNAL BAND ADJUSTMENT SYSTEM
238
226
3
3
224
222
216
212
220
210
TO ACCESS PORT

FIG.2

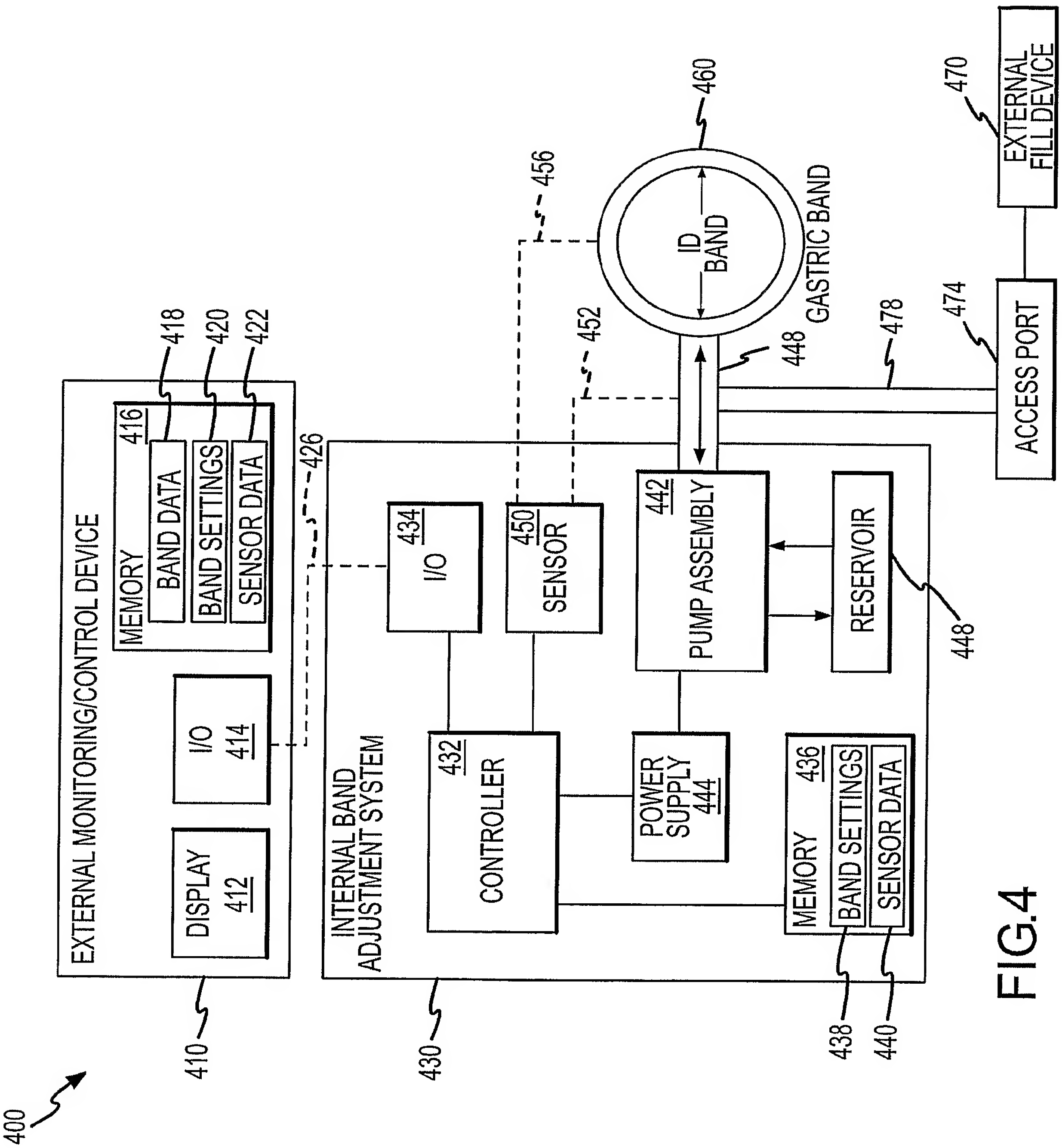

400
EXTERNAL MONITORING/CONTROL DEVICE
410
DISPLAY
412
I/O
414
MEMORY
416
BAND DATA
BAND SETTINGS
SENSOR DATA
418
420
422
426
INTERNAL BAND ADJUSTMENT SYSTEM
430
CONTROLLER
432
I/O
434
SENSOR
450
POWER SUPPLY
444
PUMP ASSEMBLY
442
RESERVOIR
448
MEMORY
436
BAND SETTINGS
SENSOR DATA
438
440
452
456
448
ID BAND
GASTRIC BAND
460
478
ACCESS PORT
474
EXTERNAL FILL DEVICE
470

FIG.4

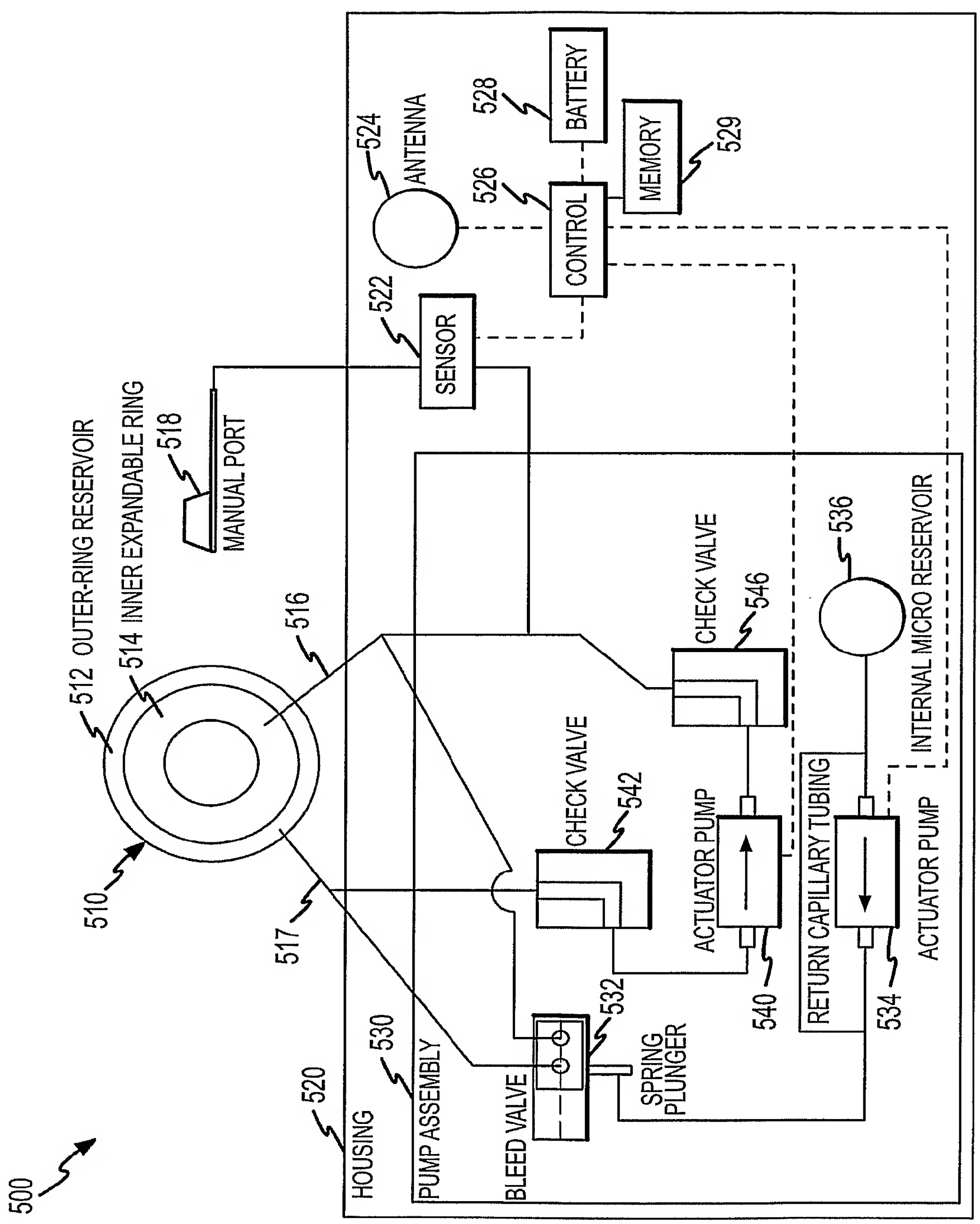

500
510
512 OUTER-RING RESERVOIR
514 INNER EXPANDABLE RING
516
517
518
MANUAL PORT
520
HOUSING
522
SENSOR
524
ANTENNA
526
CONTROL
528
BATTERY
529
MEMORY
530
PUMP ASSEMBLY
532
BLEED VALVE
SPRING PLUNGER
534
ACTUATOR PUMP
536
INTERNAL MICRO RESERVOIR
RETURN CAPILLARY TUBING
540
ACTUATOR PUMP
542
CHECK VALVE
546
CHECK VALVE

FIG.5

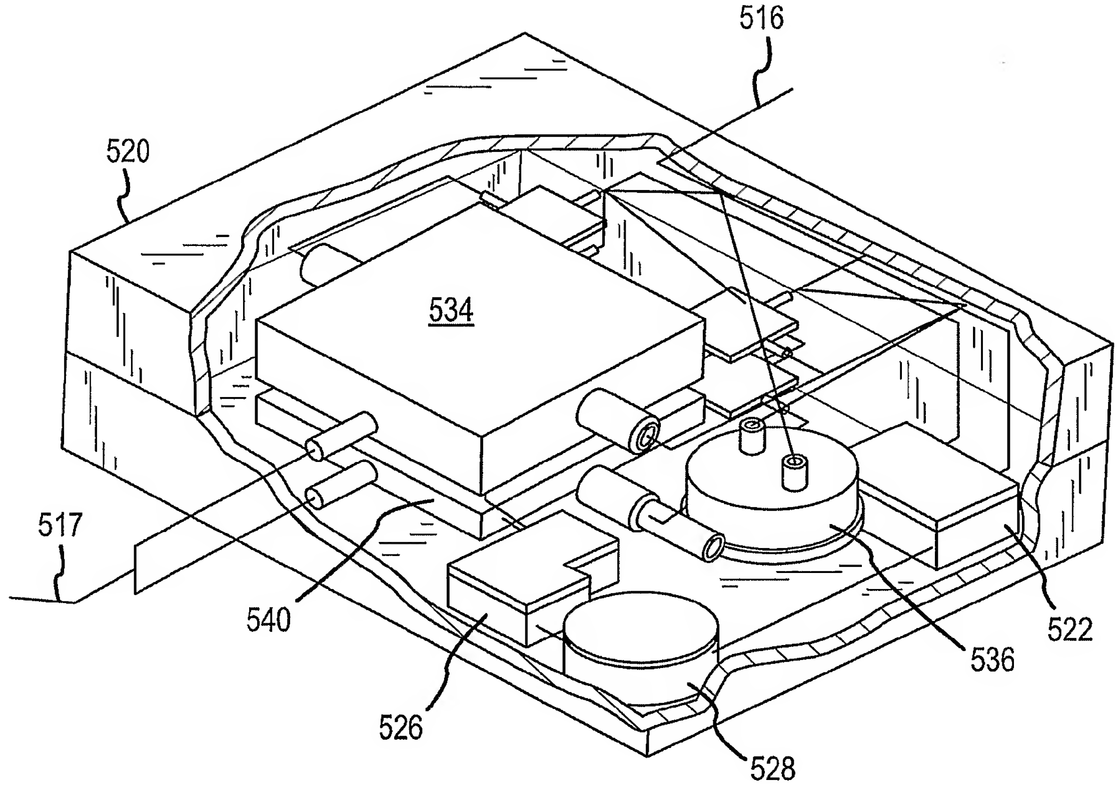


FIG.6

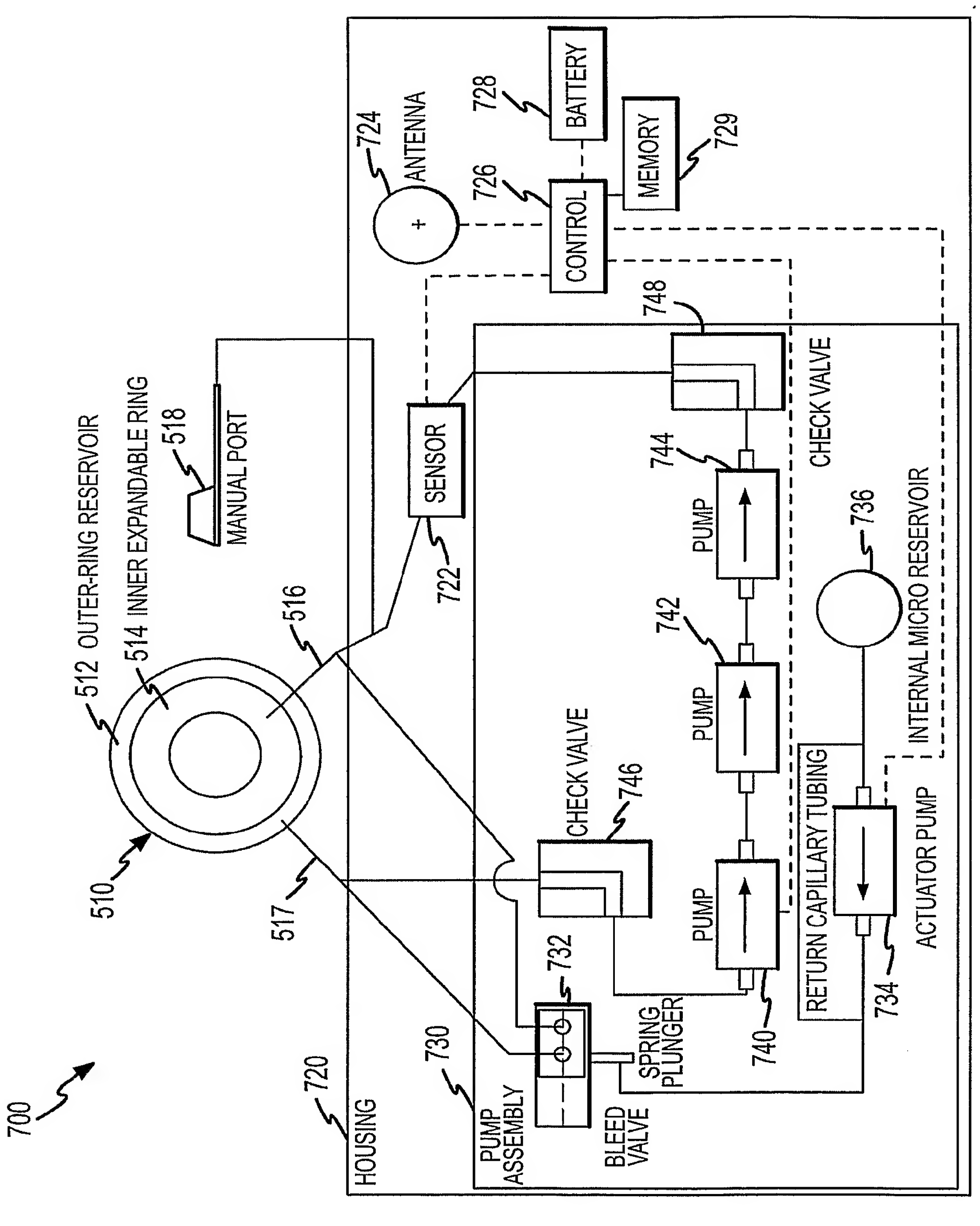

700
510
512 OUTER-RING RESERVOIR
514 INNER EXPANDABLE RING
516
517
518
MANUAL PORT
720
HOUSING
722
SENSOR
724
ANTENNA
726
CONTROL
728
BATTERY
729
MEMORY
730
PUMP ASSEMBLY
732
BLEED VALVE
SPRING PLUNGER
734
ACTUATOR PUMP
736
INTERNAL MICRO RESERVOIR
RETURN CAPILLARY TUBING
740
742
744
PUMP
PUMP
PUMP
746
CHECK VALVE
748
CHECK VALVE

FIG.7

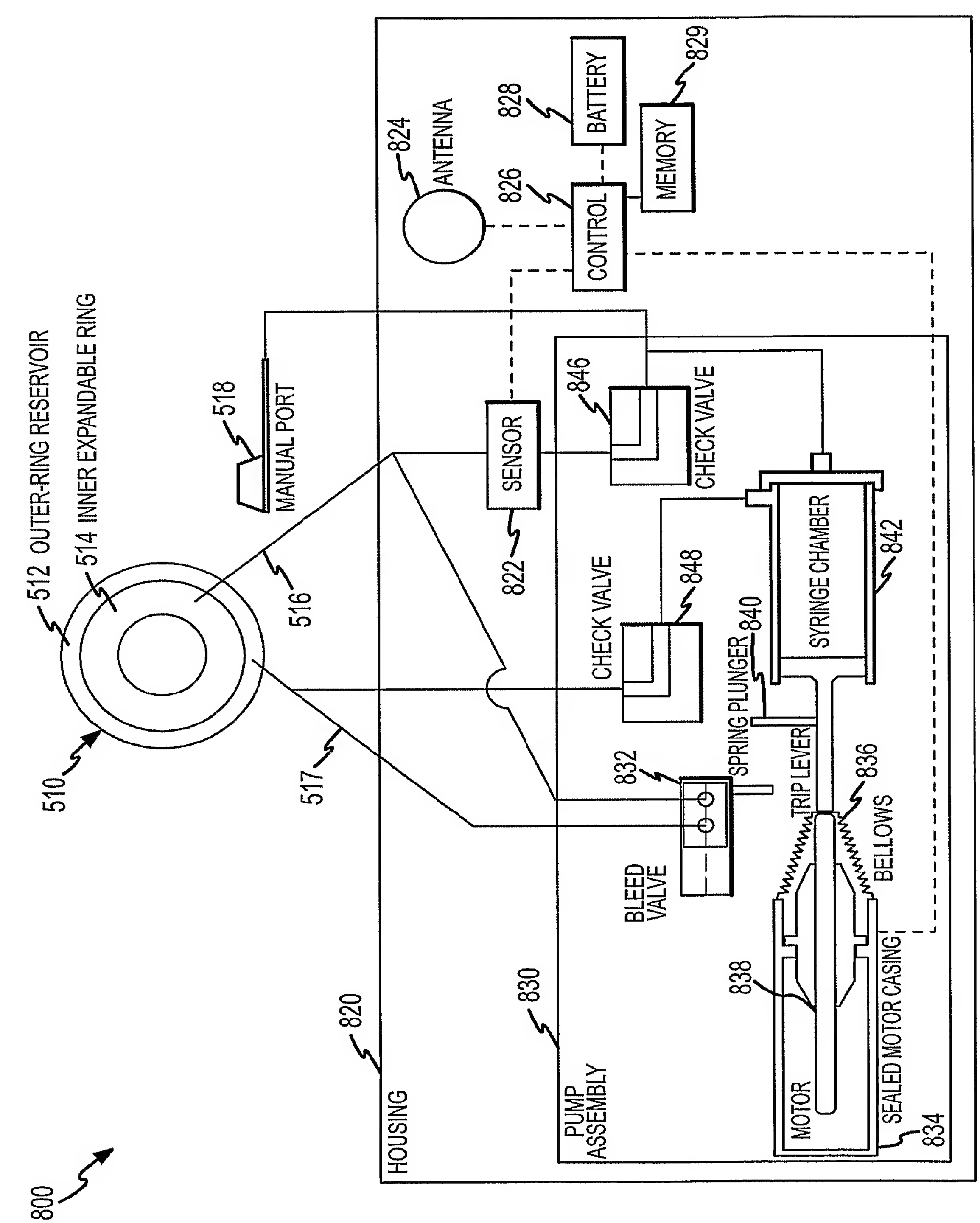
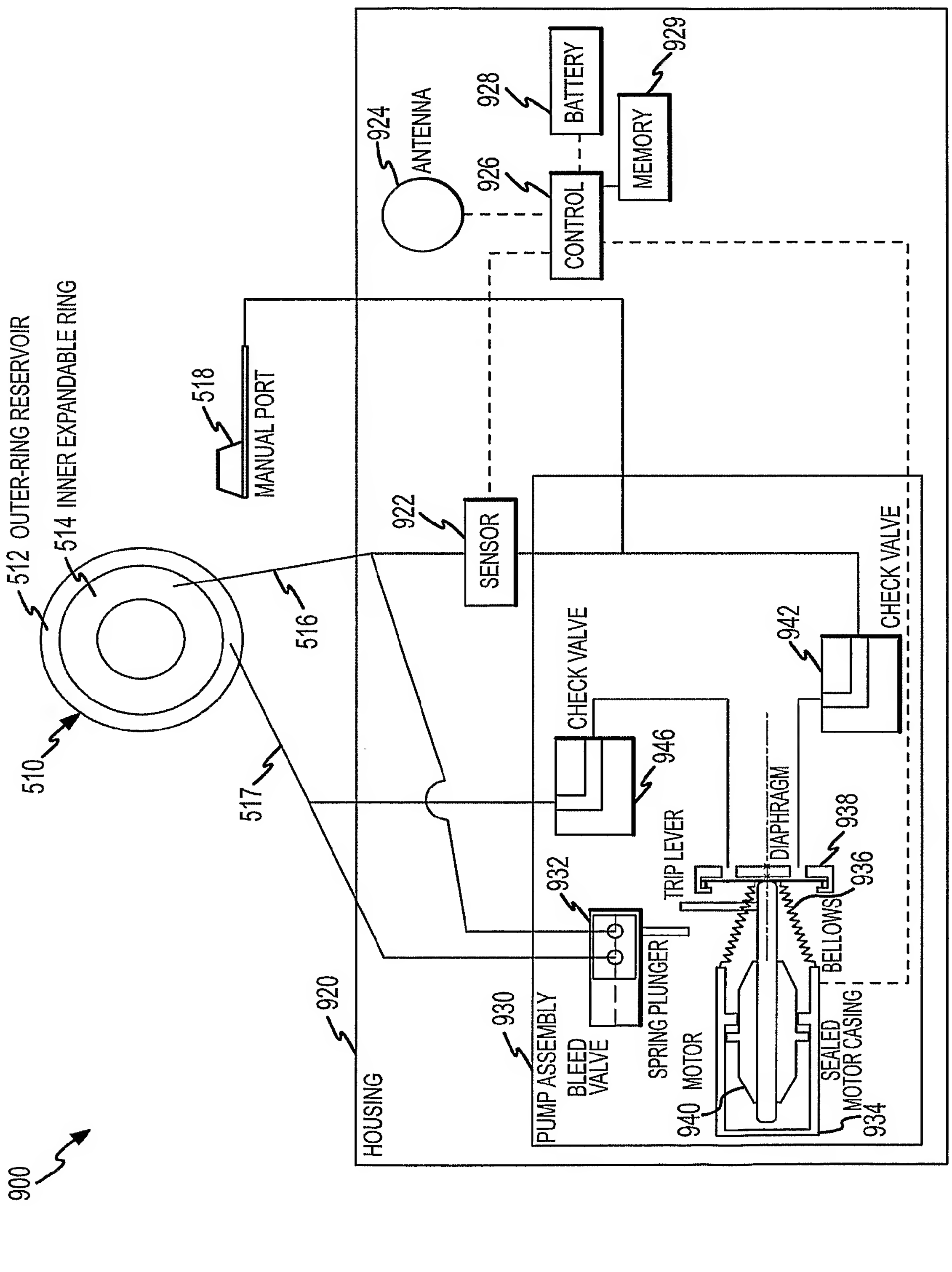
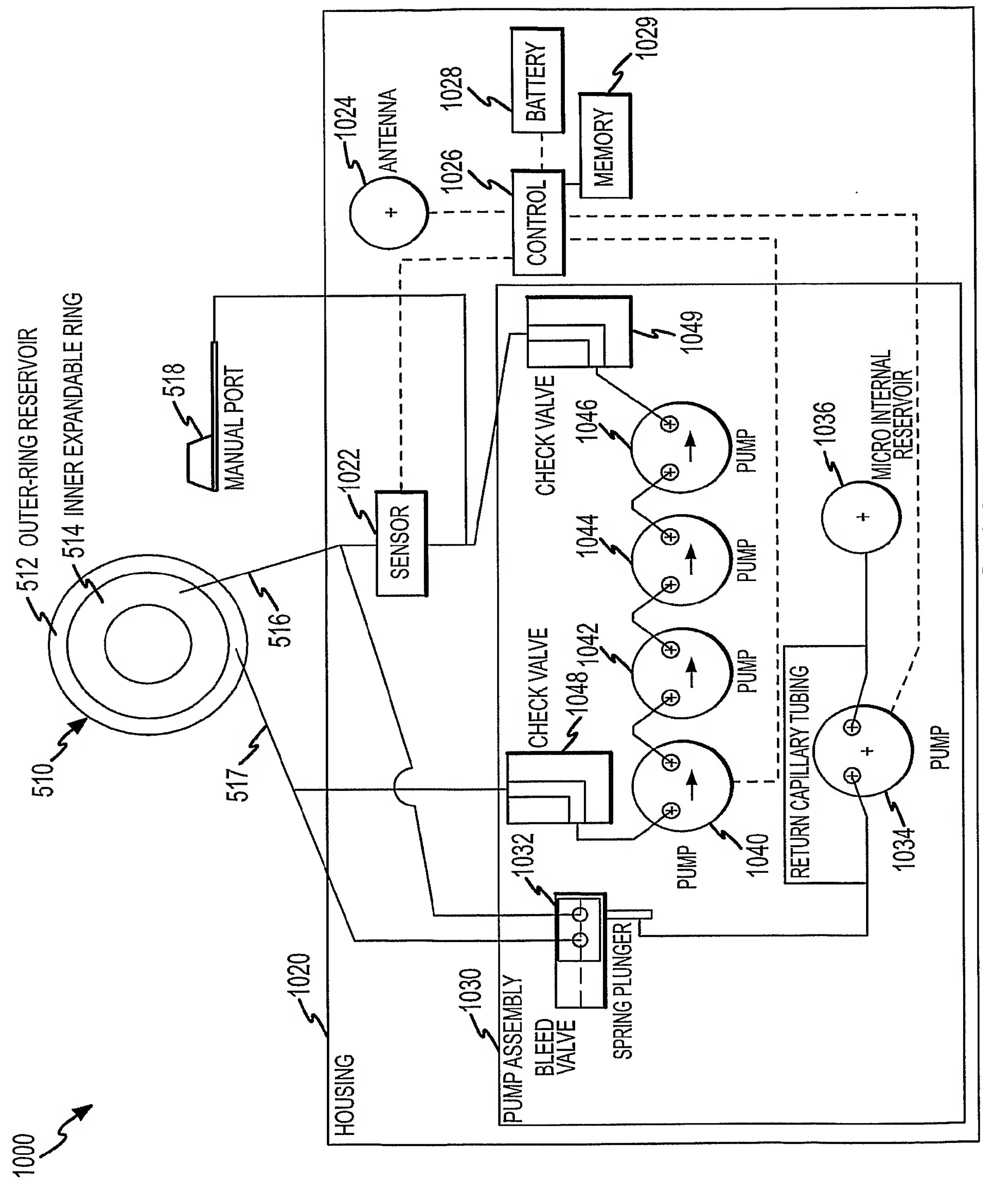

512 OUTER-RING RESERVOIR
514 INNER EXPANDABLE RING
510
516
517
518
MANUAL PORT
HOUSING
820
PUMP ASSEMBLY
830
ANTENNA
824
CONTROL
826
BATTERY
828
MEMORY
829
SENSOR
822
CHECK VALVE
846
CHECK VALVE
848
SYRINGE CHAMBER
842
SPRING PLUNGER
840
TRIP LEVER
BLEED VALVE
832
BELLOWS
836
838
MOTOR
SEALED MOTOR CASING
834
800

FIG.8



512 OUTER-RING RESERVOIR
514 INNER EXPANDABLE RING
510
516
517
518
MANUAL PORT
922
SENSOR
924
ANTENNA
926
CONTROL
928
BATTERY
929
MEMORY
CHECK VALVE
946
CHECK VALVE
942
DIAPHRAGM
TRIP LEVER
938
936
BELLOWS
932
SPRING PLUNGER
BLEED VALVE
930
PUMP ASSEMBLY
MOTOR
940
SEALED MOTOR CASING
934
920
HOUSING
900

FIG.9



512 OUTER-RING RESERVOIR
514 INNER EXPANDABLE RING
510
516
517
518
MANUAL PORT
1022
SENSOR
1024
ANTENNA
1026
CONTROL
1028
BATTERY
1029
MEMORY
1049
CHECK VALVE
1046
PUMP
1044
PUMP
1042
PUMP
1048
CHECK VALVE
1040
PUMP
1036
MICRO INTERNAL RESERVOIR
RETURN CAPILLARY TUBING
1034
PUMP
1032
SPRING PLUNGER
1030
PUMP ASSEMBLY
BLEED VALVE
1020
HOUSING
1000

FIG.10

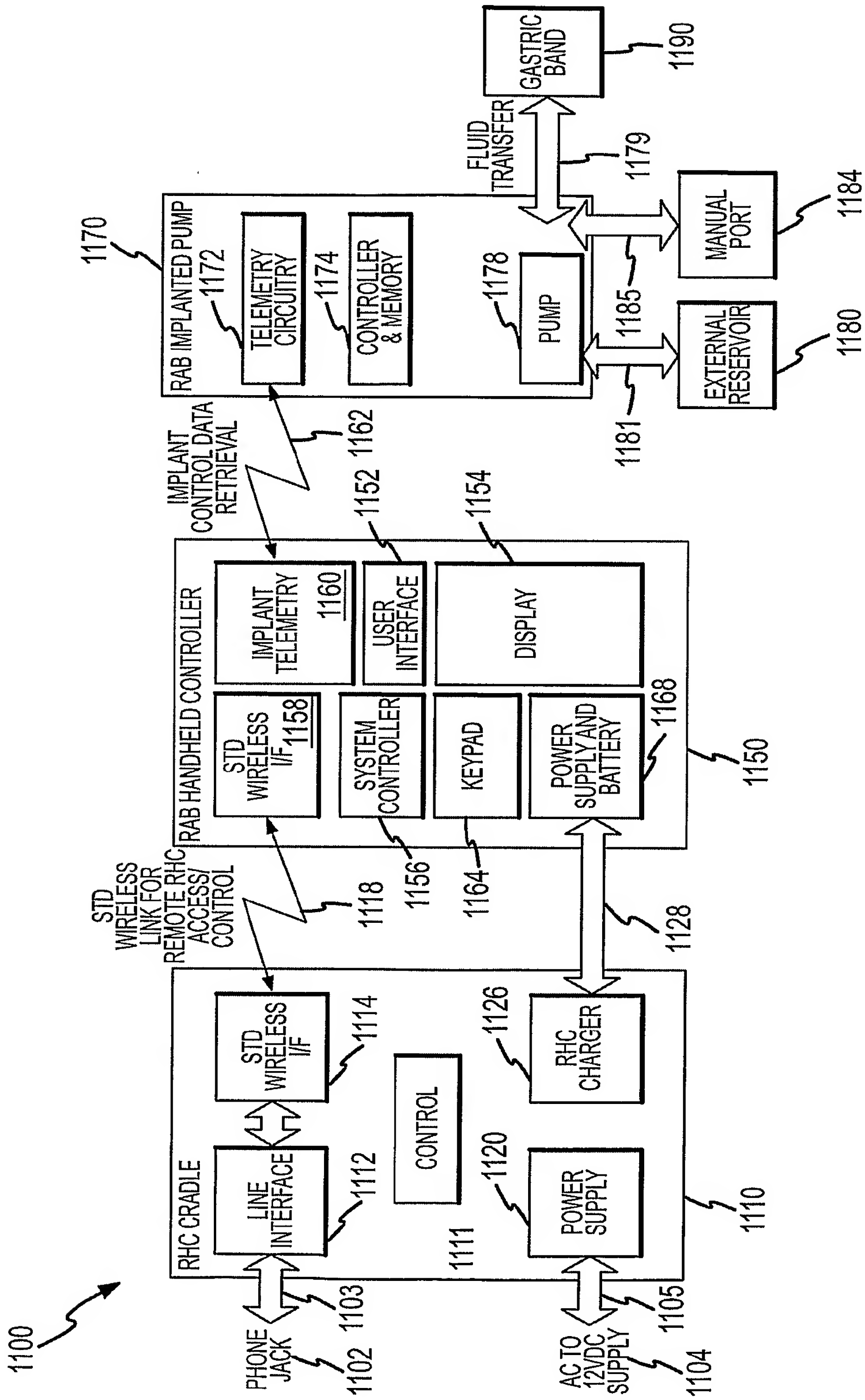
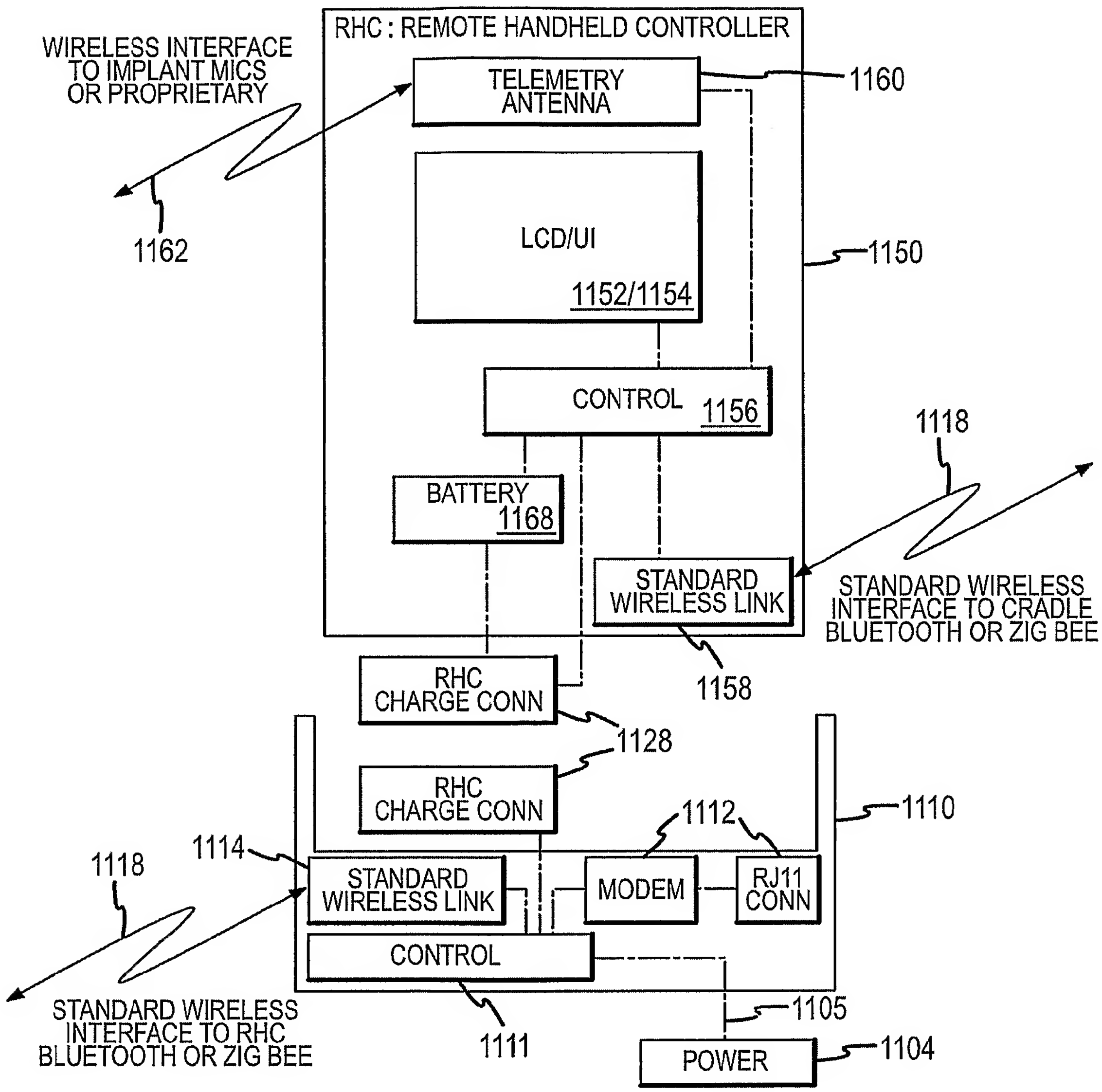

1100
RHC CRADLE
LINE INTERFACE
1112
STD WIRELESS I/F
1114
CONTROL
1111
POWER SUPPLY
1120
RHC CHARGER
1126
1110
PHONE JACK
1102
1103
AC TO 12VDC SUPPLY
1104
1105
STD WIRELESS LINK FOR REMOTE RHC ACCESS/ CONTROL
1118
1128
RAB HANDHELD CONTROLLER
STD WIRELESS I/F 1158
SYSTEM CONTROLLER
1156
KEYPAD
1164
POWER SUPPLY AND BATTERY
1168
IMPLANT TELEMETRY 1160
USER INTERFACE
1152
DISPLAY
1154
1150
IMPLANT CONTROL DATA RETRIEVAL
1162
RAB IMPLANTED PUMP
1170
TELEMETRY CIRCUITRY
1172
CONTROLLER & MEMORY
1174
PUMP
1178
FLUID TRANSFER
1179
GASTRIC BAND
1190
MANUAL PORT
1184
1185
EXTERNAL RESERVOIR
1180
1181

FIG.11



RHC : REMOTE HANDHELD CONTROLLER
WIRELESS INTERFACE TO IMPLANT MICS OR PROPRIETARY
TELEMETRY ANTENNA
1160
1162
LCD/UI
1152/1154
1150
CONTROL 1156
1118
BATTERY 1168
STANDARD WIRELESS LINK
STANDARD WIRELESS INTERFACE TO CRADLE BLUETOOTH OR ZIG BEE
1158
RHC CHARGE CONN
1128
RHC CHARGE CONN
1112
1110
1114
1118
STANDARD WIRELESS LINK
MODEM
RJ11 CONN
CONTROL
1105
STANDARD WIRELESS INTERFACE TO RHC BLUETOOTH OR ZIG BEE
1111
POWER
1104

FIG.12

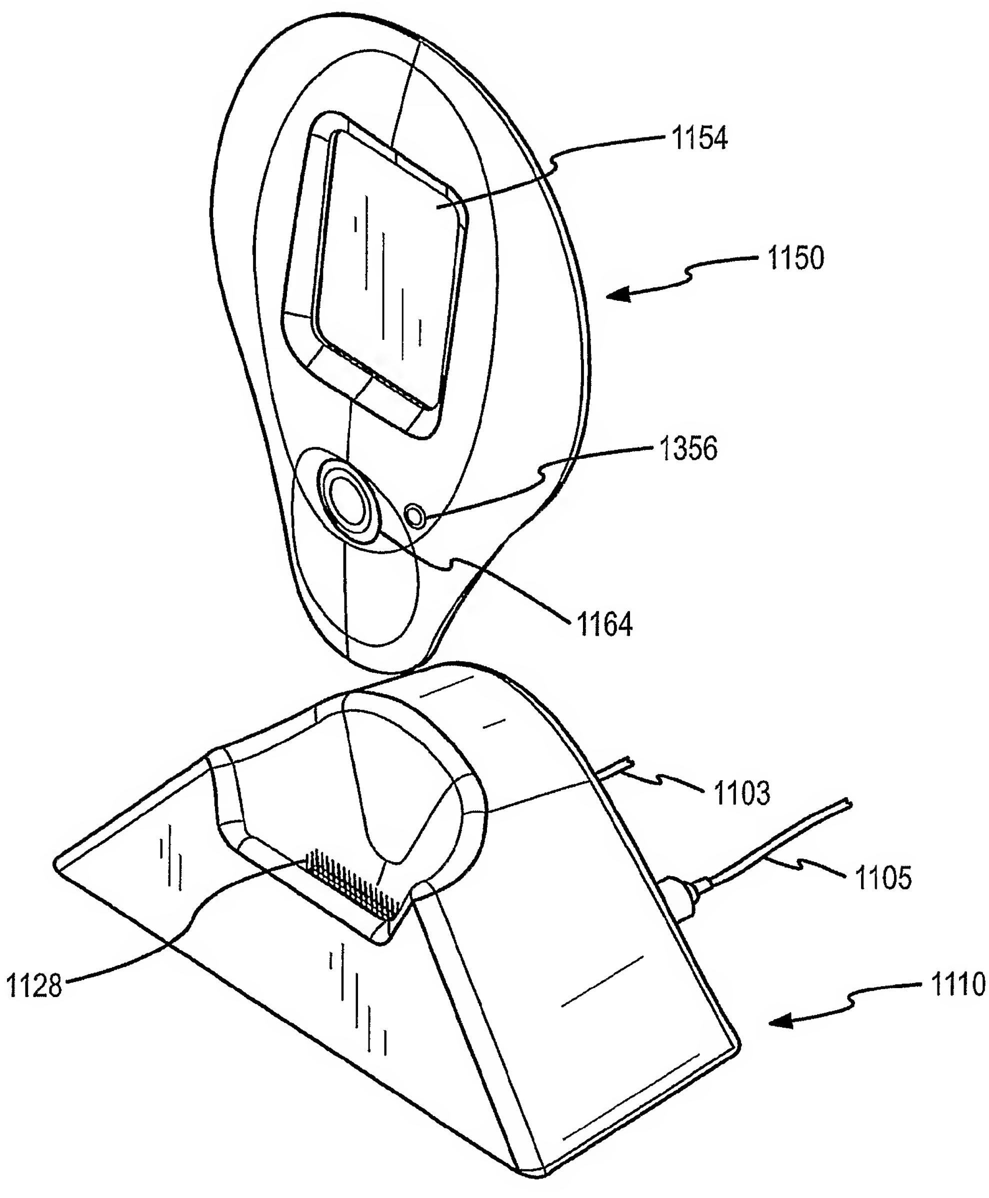


FIG.13

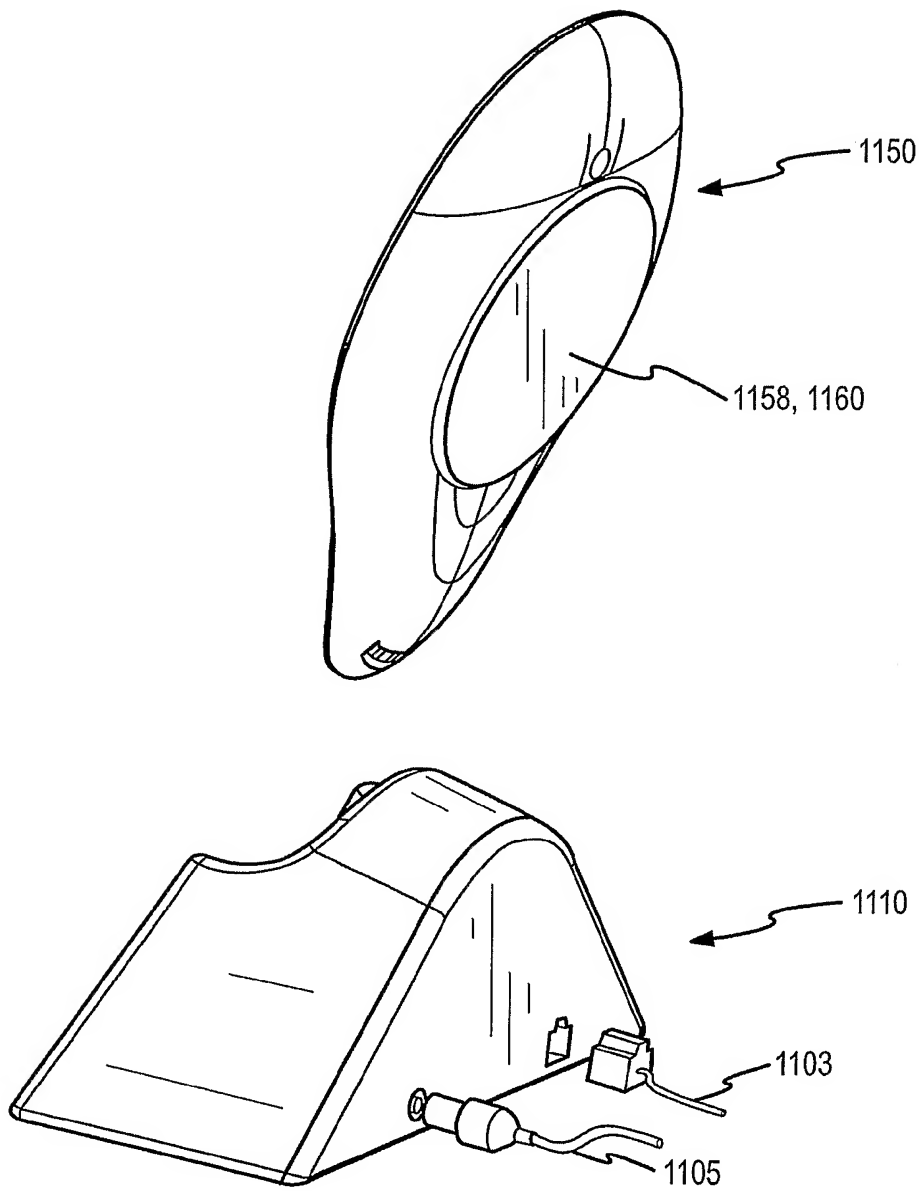


FIG.14

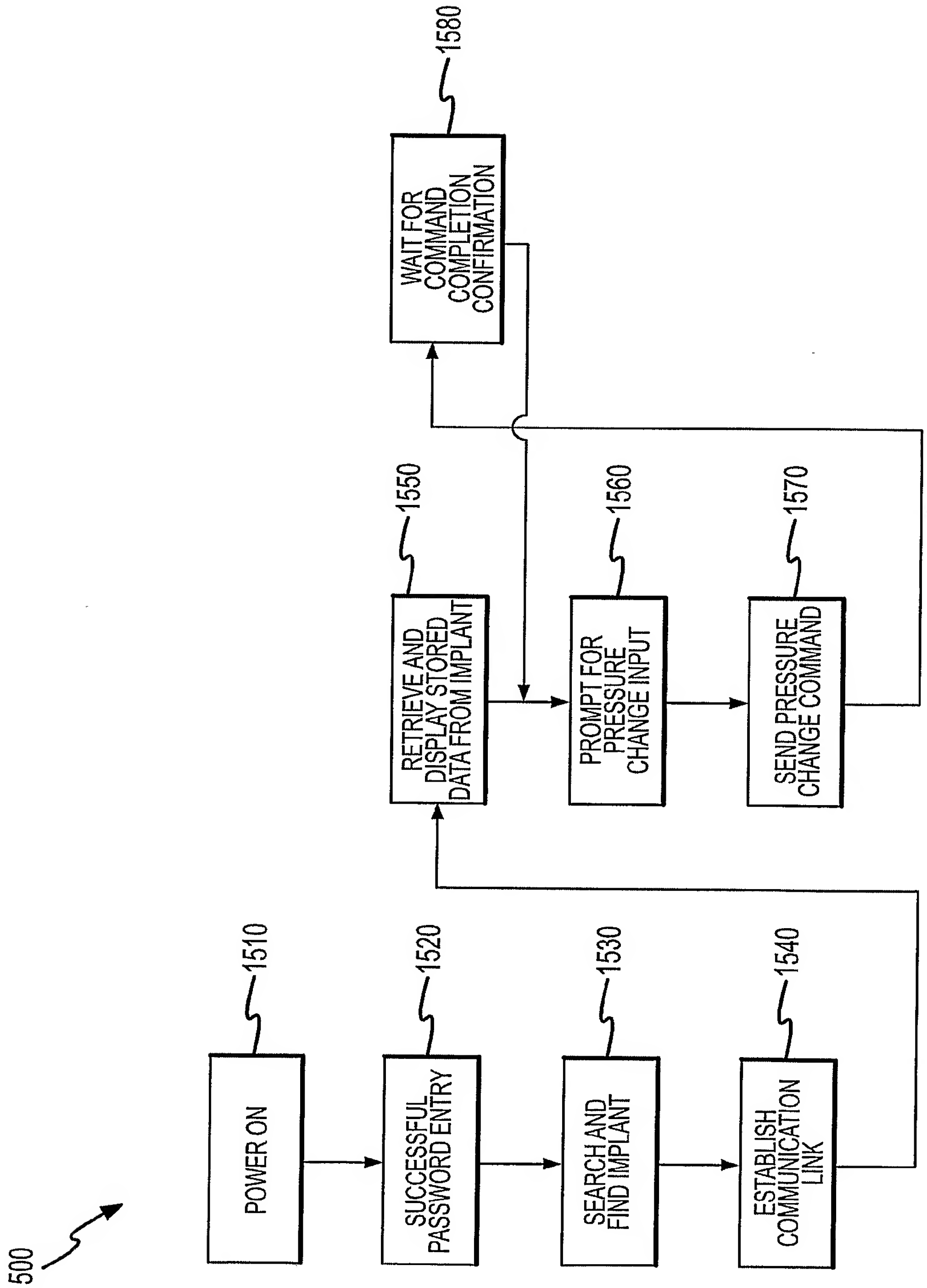

1500
POWER ON
1510
SUCCESSFUL PASSWORD ENTRY
1520
SEARCH AND FIND IMPLANT
1530
ESTABLISH COMMUNICATION LINK
1540
RETRIEVE AND DISPLAY STORED DATA FROM IMPLANT
1550
PROMPT FOR PRESSURE CHANGE INPUT
1560
SEND PRESSURE CHANGE COMMAND
1570
WAIT FOR COMMAND COMPLETION CONFIRMATION
1580

FIG.15